



STATISTICAL REPORT

TITLE: A prospective, multi-centre, controlled, double-blind study to evaluate the efficacy and tolerability of a steroid/antibiotic associated treatment following cataract extraction by means of phaco-emulsification

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Table of contents

| | |
|--|----|
| Table of contents | 2 |
| 1. Study objective..... | 3 |
| 2. Study endpoint | 3 |
| 2.1 Primary endpoint..... | 3 |
| 2.2 Secondary endpoints | 3 |
| 3. Software | 3 |
| 5. Statistical Methods..... | 4 |
| 5.1 General principles | 4 |
| 5.2 Sample Size Calculation | 5 |
| 5.3 Handling of Missing Values | 5 |
| 5.4 Schedule of assessment..... | 5 |
| 5.5 Definition of Sets for Statistical Analysis..... | 5 |
| 6. Description of analyses | 5 |
| 6.1 Overall disposition | 5 |
| 6.2 Sample profile at screening..... | 5 |
| 6.3 Evaluations at surgery | 6 |
| 6.4 Efficacy evaluation after surgery | 6 |
| 6.5 Concomitant medications..... | 6 |
| 6.6 Safety evaluation..... | 7 |
| 7. Results..... | 7 |
| 7.1 Disposition of the sample..... | 7 |
| 7.2 Protocol violation..... | 8 |
| 7.3 Population sets analyzed | 8 |
| 7.4 Comparability between the two treatment groups | 8 |
| 7.5 Baseline characteristics | 8 |
| 7.6 Evaluation at surgery | 9 |
| 7.7 Efficacy evaluation after surgery | 10 |
| 7.7.1 Primary endpoint..... | 10 |
| 7.7.2 Secondary endpoints | 12 |

1. Study objective

The objective of this study is to demonstrate the efficacy and tolerability of NETILDEX™ 3mg/ml / 1mg/ml ophthalmic gel, administered twice daily (b.i.d.), in comparison with NETILDEX™ 3mg/ml / 1mg/ml eye drops solution, administered four times a day (q.i.d.) in the prevention of post-surgery inflammation and infection after cataract extraction by means of phaco-emulsification.

2. Study endpoint

2.1 Primary endpoint

The primary objective of this study is to demonstrate the noninferiority of a reduced frequency of administration of Netildex gel, administered twice daily (b.i.d.), in comparison with Netildex drops solution, administered four times a day (q.i.d.), in the prevention of post-surgery inflammation and infection after cataract extraction.

For this evaluation has been adopted the responder rate (for the definition of responder see paragraph 6.4) measured in the comparison between the inflammation status 24 hours after surgery (Visit 3) and inflammation status after seven days (Visit 4).

2.2 Secondary endpoints

Secondary objectives of this study are:

- to confirm the antibiotic efficacy of Netildex gel after 15 days from cataract surgery (Visit 5);
- to confirm the safety of Netildex gel in terms of:
 - Intra Ocular Pressure (IOP);
 - adverse events;
 - presence or absence of conjunctival hyperemia;
- to establish the global tolerability of Netiildex gel.

3. Software

Statistical calculations will be performed using SAS System, release 9.4 in Microsoft Windows 10 Pro environment. The SAS library engine is the release V9.

4. Data management

The clinical data have provided after database lock in native format SAS (sas7bdat).

To be analyzed, original datasets have been converted to derived datasets and all categorical fields formatted. In the table of the next page, the original datasets and correspondent description are reported.

Exhibit 1: Listing of source datasets exported from SAS PheedIt database

| # | Name source dataset | Description |
|----|---------------------|--|
| 1 | AE | Adverse event |
| 2 | AE_COD | Adverse event (medical codes) |
| 3 | AE_YN | Adverse event (n/y) |
| 4 | AMSLER | Amsler test |
| 5 | ANTI_AFTER | Antibiotics after surgery |
| 6 | ANTI_AFTER_COD | Antibiotics after surgery (medical codes) |
| 7 | ANTI_AFTER_YN | Antibiotics after surgery (n/y) |
| 8 | ANTI_BEFORE | Antibiotics before surgery |
| 9 | ANTI_BEFORE_COD | Antibiotics before surgery (medical codes) |
| 10 | ANTI_BEFORE_YN | Antibiotics before surgery (n/y) |
| 11 | ANTIBIOGRAM | Microbial load |
| 12 | BROM_TRT | Bromfenac treatment during the 3 days before surgery |
| 13 | CMED | Concomitant medications |
| 14 | CMED_COD | Concomitant medications (medical codes) |
| 15 | CMED_YN | Concomitant medications (n/y) |
| 16 | DEMOGRAPHY | Demography, Informed consent |
| 17 | EOS | End of study |
| 18 | EXCLUSION | Exclusion criteria |
| 19 | INCLUSION | Inclusion criteria |
| 20 | INTRA_PRES | Intra ocular pressure |
| 21 | MEDHIS | General medical history |
| 22 | MEDHIS_COD | General medical history (medical codes) |
| 23 | MEDHIS_YN | General medical history (n/y) |
| 24 | MICRO_LOAD | Microbial load |
| 25 | MYDRIATIC_COD | Mydriatic drugs during the study (medical codes) |
| 26 | MYDRIATIC | Mydriatic drugs during the study |
| 27 | MYDRIATIC_YN | Mydriatic drugs during the study (n/y) |
| 28 | OCT | Optical Coherence Tomography test |
| 29 | OCULAR_INFLA | Evaluation of signs/symptoms of ocular inflammation |
| 30 | OPHHIS | Ophtalmic medical history |
| 31 | OPHHIS_COD | Ophtalmic medical history (medical codes) |
| 32 | OPHHIS_YN | Ophtalmic medical history (n/y) |
| 33 | OPHTHALMOSCOPY | Ophtalmoscopy test |
| 34 | PREGNANCY | Pregnancy test |
| 35 | RAND | Randomization |
| 36 | SLIT | SLIT lamp examination |
| 37 | SURGERY | Cataract surgery |
| 38 | TOLERABILITY | Evaluation of global tolerability by investigator |
| 39 | TREATMENT | Study treatment after surgery |
| 40 | UNS_REAS | Reason for unscheduled visit |
| 41 | VISIT | Date of visit |
| 42 | VISUAL_CONTROL | Visual acuity at control visits |
| 43 | VISUAL_SCREEN | Visual acuity at the screening visit |

5. Statistical Methods

Planned analyses for this study have been outlined in the Statistical Analysis Plan (SAP).

5.1 General principles

All the variables collected have been summarized by appropriate descriptive statistics: mean, standard deviation, median, minimum and maximum for continuous variables; frequency and per cent values for categorical variables.

The primary objective has been evaluated in the Intention-To-Treat (ITT) population and one-tailed alpha level of 0.025 has been used for the statistical test.

5.2 Sample Size Calculation

Considering a true difference in the evaluation of the responder rate in favour of the reference treatment of 5%, then 130 Patients are required to be 90% sure that the lower limit of a one-sided 97.5% Confidence Interval will exclude a difference in favour of the reference group of more than 10%. Considering a drop-out rate of 28%, the global sample size will be at least of 180 subjects.

5.3 Handling of Missing Values

No missing data imputations techniques have been used.

5.4 Schedule of assessment

The study assessments and data collection have been performed at the following visits:

1. visit 1 (day -4/-7, before cataract surgery) - screening
2. visit 2 (day 0) - surgery
3. visit 3 (day 1) - control 1
4. visit 4 (day 7±1) - control 2
5. visit 5 (day 15±2) - end of treatment

5.5 Definition of Sets for Statistical Analysis

Intent-To-Treat (ITT) analysis population

The Intent-To-Treat (ITT) analysis population is intended as the set of Patients who received the dose of study treatment and presence of SLIT lamp examination at baseline Visit 3 (day 1) and endpoint Visit 4 (day 7). This population is considered as primary and will be used for all efficacy analyses.

Per-Protocol (PP) analysis population

The Per-Protocol (PP) population will include all ITT patients who completed regularly the study with no major violations of the eligibility criteria or during study conduction. This population will be used as a sensitivity analysis for the comparison of the results respect to the ITT analysis limited to the primary endpoint.

Safety Analysis Population

The Safety Analysis Population will include all Patients registered, who received at least one dose of study treatment. This population will be used for safety analysis. Patients will be analysed according to the treatment to which they were randomised.

6. Description of analyses

6.1 Overall disposition

Descriptive tables for:

- patient accountability (treated, completers, withdrawn);
- protocol violations;
- sample disposition;
- patient stratification by Age and Sex;
- time intervals.

6.2 Sample profile at the screening

Descriptive assessment of:

- demography (sex, age, race);
- baseline clinical tests (IOP, SLIT lamp, Ophtalmoscopy test);
- medical and ophtalmoscopy history;
- use of antibiotics before surgery.

6.3 Evaluations at the surgery

Descriptive tables for:

- use of Bromfenac medication;
- sterilization;
- surgery problems;
- mydriatic and antibiotic medications.

6.4 Efficacy evaluation after surgery

As previously defined (see paragraph 2.1) the primary objective of this study is to demonstrate the noninferiority of the Netildex gel in comparison with Netildex drops solution.

The efficacy parameter utilized has been the combination of two clinical parameters, *Flare* and *Cellularity* after 24 hours (Visit 3) and after 7 days (Visit 4) from cataract extraction, examined with slit lamp and bio-microscopy in the anterior ocular chamber.

In relation to the above mentioned variables, a patient has been defined:

- ✓ *Full responder*: if both measurements are responder;
- ✓ *Partial responder*: if responder at least for one of the two measurements;
- ✓ *No responder*: if both measurements are not responder.

The above classification has been used for the descriptive analyses while it has been reduced to the binary outcome (*Full responder* vs *Not Full responder*) for inferential analysis.

The hypotheses for noninferiority has been stated in terms of the difference in the proportions $D = p_{test} - p_{ctrl}$ where *test* is Netildex gel and *ctrl* is Netildex drops solution.

The null and alternative hypotheses are the following:

$$H_0: D = p_{test} - p_{ctrl} \leq -\delta$$

$$H_A: D = p_{test} - p_{ctrl} > -\delta$$

where $\delta > 0$ is the noninferiority margin of clinical interest.

A noninferiority analysis to obtain the difference in the proportion planned has been performed using the Proc Freq in SAS v. 9.4, with one-sided 97.5% Confidence Intervals and noninferiority margin of 0.10.

A Logistic Regression analysis has been done to compare the treatment effects adjusted for the variables SEX and AGE (potential confounders).

The following descriptive tables, and inference, when planned, have been performed for:

- SLIT lamp
- overall and stratified (by sex, age and site) responder rate at endpoint visit;
- Flare;
- Cellularity;
- Flare for the sub-group of patients showing a grade greater than zero at Visit 3 (day 1);
- Cellularity for the sub-group of patients showing a grade greater than zero at Visit 3 (day 1);
- Microbial load.

6.5 Concomitant medications

Descriptive assessment has been prepared for concurrent medications.

6.6 Safety evaluation

Descriptive tables of point estimation and change from Visit 1 or Visit 3, if pertinent, for:

- IOP for treated and not-treated eye;
- IOP difference between treated and not-treated eye;
- ophthalmoscopy test;
- visual acuity;
- ocular inflammation;
- global tolerability;
- AE, drug related AE and AE requiring study discontinuation.

7. Results

It was screened a sample of 176 patients in 5 centres located in Italy (3 centres) and Germany (2 centres). The patients 100103, 100240 and 200201 were considered as screening failure and received no study drug. The patients 100308, 100313, 100337, randomized in the GEL group, and the patients 100306 and 200114, randomized in the DROP group, have not been treated and not considered in this analysis.

The total number of patients remaining was 168, 85 for the GEL group and 83 for the DROP group.

Only two patients presented protocol violations and excluded from the Per-Protocol analyses:

100302 (GEL group) for violation of exclusion criteria 5 (suffering of type 2 Diabetes Mellitus)

100348 (GEL group) for violation of inclusion criteria 2 (age < 40 years)

7.1 Disposition of the sample

The percentage of premature discontinued patients was 4.2% (5.9% for GEL group and 2.4% for DROP group) where the main reason was *Withdrawal of consent* with 71.4% on total discontinued patients (80.0% for GEL group and 50.0% for DROP group).

Table 7.1-1: Subjects disposition

| | GEL (N=85) | | DROP (N=83) | | ALL (N=168) | |
|---|---------------|-------|----------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Randomized | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Completed study | 80 | 94.1 | 81 | 97.6 | 161 | 95.8 |
| Discontinued | 5 | 5.9 | 2 | 2.4 | 7 | 4.2 |
| Main reason for study discontinuation - (n %) | | | | | | |
| Withdrawal of consent/Patient choice | 4 | 80.0 | 1 | 50.0 | 5 | 71.4 |
| Adverse event | 1 | 20.0 | 1 | 50.0 | 2 | 28.6 |
| Major complications during cataract surgery | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Lack of efficacy | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Protocol violation, including disallowed conc | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Investigator considers it not in the patient' | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Sponsor terminates the study | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 5 | 100.0 | 2 | 100.0 | 7 | 100.0 |

Source table(s): 1.2

7.2 Protocol violation

Only two patients (1.5% on total), both belonging to GEL group, were classified as violators. See the listing below.

Table 7.2-1: Protocol violation patients

| Age | | | |
|--------|-------|--------|--|
| Pat.ID | (yrs) | Sex | Violation reported on database |
| 100302 | 61 | male | Patient suffering of type 2 Diabetes Mellitus (exclusion criteria 5) |
| 100348 | 38 | female | Patient age < 40 years old (inclusion criteria 2) |

Source table(s): 1.3

7.3 Population sets analyzed

The two treatment groups are well balanced, see Table 7.3-1. The listing of not-regular patients is depicted in Appendix 1 on page 11.

Table 7.3-1: Summary of patient sets disposition

| | GEL (N=88) | DROP (N=85) | ALL (N=173) |
|----------------------|---------------|----------------|----------------|
| No. of patients | n % | n % | n % |
| Screened | | | 176 100.0 |
| Screening failure | | | 3 1.7 |
| Randomized | 88 100.0 | 85 100.0 | 173 100.0 |
| Non treated patients | 3 3.4 | 2 2.4 | 5 2.9 |
| Treated patients | 85 96.6 | 83 97.6 | 168 97.1 |
| Treated patients | 85 100.0 | 83 100.0 | 168 100.0 |
| Safety population | 85 100.0 | 83 100.0 | 168 100.0 |
| ITT population | 80 94.1 | 80 96.4 | 160 95.2 |
| PP population | 78 91.8 | 80 96.4 | 158 64.0 |

Source table(s): 1.4

See Table 1.5 of Appendix 1 for the sample disposition when stratified by Sex and Age.

7.4 Comparability between the two treatment groups

The two groups do not show significant differences.

7.5 Baseline characteristics

A preponderance of females (62.5% on total) but not statistically significative.

See Table 7.5-1 on the next page.

Table 7.5-1: Demographic characteristics

| Variable | GEL (N=85) | | DROP (N=83) | | ALL (N=168) | | Difference between study drugs | 95% CI of difference |
|-----------------------|---------------|-------|----------------|-------|----------------|-------|--------------------------------------|-------------------------|
| | n | % | n | % | n | % | | |
| Age (years) | | | | | | | -0.9931 | -3.6090 1.6229 |
| N | 85 | | 83 | | 168 | | | |
| Mean | 72.2 | | 73.2 | | 72.7 | | | |
| SD | 8.8 | | 8.3 | | 8.6 | | | |
| Median | 74.0 | | 74.0 | | 74.0 | | | |
| Range | 38.0 | 89.0 | 48.0 | 89.0 | 38.0 | 89.0 | | |
| Age frequency - (n %) | | | | | | | | |
| <=65 | 16 | 18.8 | 15 | 18.1 | 31 | 18.5 | | |
| 66-74 | 37 | 43.5 | 28 | 33.7 | 65 | 38.7 | | |
| >=75 | 32 | 37.6 | 40 | 48.2 | 72 | 42.9 | | |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 | | |
| Sex - (n %) | | | | | | | 12.2000 | -2.3100 26.7200 |
| Male | 37 | 43.5 | 26 | 31.3 | 63 | 37.5 | | |
| Female | 48 | 56.5 | 57 | 68.7 | 105 | 62.5 | | |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 | | |
| Race - (n %) | | | | | | | | |
| White | 84 | 98.8 | 81 | 97.6 | 165 | 98.2 | | |
| Black | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 | | |
| Asian | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | | |
| Middle-eastern | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | | |
| Other | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | | |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 | | |

Source table(s): 2.1

All the patients performed AMSLER and OCT test, with negative results. No significant difference between groups about the variables Visual acuity, IOP and SLIT lamp.

See Table 2.2 of Appendix 1.

No relevant abnormalities percentages for the variable Ophtalmoscopy test were noted, only 2.4% for Retina and 1.8% for Choroid of the whole sample, showed an abnormality.

See Table 2.3 of Appendix 1.

About 71.4% of the total of the sample (69.4% for GEL group and 73.5% for DROP group) showed a relevant Medical history.

See Table 2.4 of Appendix 1.

About 20.8% of the total of the sample (21.2% for GEL group and 20.5% for DROP group) showed a relevant Ophtalmoscopy history.

See Table 2.5 of Appendix 1.

About 55.4% of the total of the sample (54.1% for GEL group and 56.6% for DROP group) have assumed antibiotic medications before surgery.

See Table 2.6 of Appendix 1.

7.6 Evaluation at the surgery

The whole sample, except one patient, have assumed Bromfenac medication before surgery.

See Table 3.1 of Appendix 1.

No problem during surgery has been reported.

See Table 3.2 of Appendix 1.

About 98.8% of the total of the sample (97.6% for GEL group and 100.0% for DROP group) have assumed mydiatic medication at the surgery, and about 24.4% (22.4% for GEL group and 26.5% for DROP group) have assumed antibiotic medications after surgery.

See Table 3.3-1 of Appendix 1.

Regarding the evaluation of ocular inflammation at the surgery, we can see that the two treatment groups are similar. See table 7.6-1 below.

Table 7.6-1: Ocular inflammation at the surgery

| Variable | GEL (N=85) | | DROP (N=83) | | ALL (N=168) | |
|---|---------------|-------|----------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Anterior chamber flare - (n %) | | | | | | |
| None | 57 | 73.1 | 54 | 71.1 | 111 | 72.1 |
| Faint | 21 | 26.9 | 22 | 28.9 | 43 | 27.9 |
| Total | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |
| Conjunctival hyperemia - (n %) | | | | | | |
| None | 71 | 91.0 | 73 | 96.1 | 144 | 93.5 |
| Mild | 7 | 9.0 | 3 | 3.9 | 10 | 6.5 |
| Total | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |
| Ocular discomfort: pain - (n %) | | | | | | |
| None | 77 | 98.7 | 76 | 100.0 | 153 | 99.4 |
| Mild | 1 | 1.3 | 0 | 0.0 | 1 | 0.6 |
| Total | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |
| Ocular discomfort: photophobia - (n %) | | | | | | |
| None | 69 | 88.5 | 67 | 88.2 | 136 | 88.3 |
| Mild | 9 | 11.5 | 9 | 11.8 | 18 | 11.7 |
| Total | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |
| Ocular discomfort: tearing - (n %) | | | | | | |
| None | 68 | 87.2 | 69 | 90.8 | 137 | 89.0 |
| Mild | 10 | 12.8 | 7 | 9.2 | 17 | 11.0 |
| Total | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |

Source table(s): 3.4

7.7 Efficacy evaluation after surgery

As previously reported (see paragraph 6.4) the objective of this study is to demonstrate the noninferiority of the Netildex gel in comparison with Netildex drops solution.

7.7.1 Primary endpoint

The primary endpoint was the combination of the grade of severity of two clinical parameters, *Flare* and *Cellularity* after 24 hours and after 7 days (Visit 4) from surgery.

Given the following definition:

- ✓ *Full responder*: if both measurements are responder;
- ✓ *Partial responder*: if responder at least for one of the two measurements;
- ✓ *No responder*: if both measurements are not responder.

where *responder* was the patient with a decrease of the degree at endpoint respect to baseline or absence of degree both at baseline and at endpoint visits.

Now we describe the situation of the two clinical variables separately, Cellularity and Flare, which compose the primary endpoint (see Table 7.7-1-1 in the next page).

Table 7.7-1-1: Cellularity and Flare

| Variable | Visit | GEL (N=80) | | DROP (N=80) | | ALL (N=160) | |
|--------------------|---------------------|------------|-------|-------------|-------|-------------|-------|
| | | n | % | n | % | n | % |
| Cellularity | | | | | | | |
| | V4 (day 7) - (n %) | | | | | | |
| | decreased | 8 | 10.0 | 8 | 10.0 | 16 | 10.0 |
| | unchanged | 71 | 88.8 | 72 | 90.0 | 143 | 89.4 |
| | increased | 1 | 1.3 | 0 | 0.0 | 1 | 0.6 |
| | total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| | V5 (day 15) - (n %) | | | | | | |
| | decreased | 10 | 12.5 | 9 | 11.3 | 19 | 11.9 |
| | unchanged | 70 | 87.5 | 71 | 88.8 | 141 | 88.1 |
| | increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| | total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| Flare | | | | | | | |
| | V4 (day 7) - (n %) | | | | | | |
| | decreased | 17 | 21.3 | 24 | 30.0 | 41 | 25.6 |
| | unchanged | 63 | 78.8 | 56 | 70.0 | 119 | 74.4 |
| | increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| | total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| | V5 (day 15) - (n %) | | | | | | |
| | decreased | 22 | 27.5 | 27 | 33.8 | 49 | 30.6 |
| | unchanged | 58 | 72.5 | 53 | 66.3 | 111 | 69.4 |
| | increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| | total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |

Source table(s): 4.2-1 and 4.3-1

After 7 days, we observe a very low increase of the severity degree for both the variables while this increase is absent after 14 days.

Combining the two clinical variables Cellularity and Flare, according to the definition provided previously, we observe a full response on 90% for GEL group and 95% for DROP group. See the table below.

Table 7.7-1-2: Summary of responder rate

| | GEL (N=80) | | DROP (N=80) | | ALL (N=160) | |
|-----------------------|------------|-------|-------------|-------|-------------|-------|
| | n | % | n | % | n | % |
| full responder | | | | | | |
| full responder | 72 | 90.0 | 76 | 95.0 | 148 | 92.5 |
| partial responder | 8 | 10.0 | 4 | 5.0 | 12 | 7.5 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |

Source table(s): 4.4-1

Considering the non-inferiority margin equal to 0.10, established by protocol, the test provides the following results depicted in Table 7.7-1-3.

Table 7.7-1-3: Noninferiority test on responder rate

| Source | n/N | % | Non | Test | Observed | 97.5% | |
|------------|-------|------|--------------------|-------------------|-----------------|---------------------|--------|
| | | | inferiority margin | | risk difference | Confidence interval | Lower |
| GEL | | | | | | | |
| GEL | 72/80 | 90.0 | -0.10 | Univariate test | -0.0500 | -0.0580 | 0.1580 |
| DROP | 76/80 | 95.0 | | Multivariate test | -0.0576 | -0.0378 | 0.1530 |

Source table(s): 4.5-1

The results show that the success rate for the GEL group exceeded that of the DROP group by 0.05.

The noninferiority test results indicate that the GEL group is noninferior to the DROP group since the lower limit of the 97.5% Confidence Interval (both in unadjusted and adjusted analysis) is greater than the noninferiority limit of -0.10.

When correct, the effect of study drug by the factors Sex and Age (the factor Site was not introduced in the model due to a very small number of patients) the noninferiority is confirmed (lower 97.5% CI=-0.0597).

For details see Tables 4.5-1 and 4.5-2 of Appendix 1.

7.7.2 Secondary endpoints

Evaluation of responders for the Per Protocol sample

As previously mentioned (paragraph 7.) only two patients were excluded from the PP sample (both of GEL group). The description of the two clinical variables separately, Cellularity and Flare, is reported in the Table 7.7-2-1.

No relevant differences in the results with the analysis on ITT sample.

Table 7.7-2-1: Cellularity and Flare for the PP sample

| | | GEL (N=78) | | DROP (N=80) | | ALL (N=158) | |
|--------------------|---------------------|------------|-------|-------------|-------|-------------|-------|
| Variable | Visit | n | % | n | % | n | % |
| Cellularity | | | | | | | |
| | V4 (day 7) - (n %) | | | | | | |
| | decreased | 8 | 10.3 | 8 | 10.0 | 16 | 10.1 |
| | unchanged | 69 | 88.5 | 72 | 90.0 | 141 | 89.2 |
| | increased | 1 | 1.3 | 0 | 0.0 | 1 | 0.6 |
| | total | 78 | 100.0 | 80 | 100.0 | 158 | 100.0 |
| | | | | | | | |
| | V5 (day 15) - (n %) | | | | | | |
| | decreased | 10 | 12.8 | 9 | 11.3 | 19 | 12.0 |
| | unchanged | 68 | 87.2 | 71 | 88.8 | 139 | 88.0 |
| | increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| | total | 78 | 100.0 | 80 | 100.0 | 158 | 100.0 |
| Flare | | | | | | | |
| | V4 (day 7) - (n %) | | | | | | |
| | decreased | 17 | 21.8 | 24 | 30.0 | 41 | 25.0 |
| | unchanged | 61 | 78.2 | 56 | 70.0 | 117 | 74.1 |
| | increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| | total | 78 | 100.0 | 80 | 100.0 | 158 | 100.0 |
| | | | | | | | |
| | V5 (day 15) - (n %) | | | | | | |
| | decreased | 22 | 28.2 | 27 | 33.8 | 49 | 31.0 |
| | unchanged | 56 | 71.8 | 53 | 66.3 | 109 | 69.0 |
| | increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| | total | 78 | 100.0 | 80 | 100.0 | 158 | 100.0 |

ffffffffff

Table 7.7.2.2: Summary of responder rates for the RR example

| | GEL (N=78) | | DROP (N=80) | | ALL (N=158) | |
|-------------------|---------------|-------|----------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| full responder | 70 | 89.7 | 76 | 95.0 | 146 | 92.4 |
| partial responder | 8 | 10.3 | 4 | 5.0 | 12 | 7.6 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 78 | 100.0 | 80 | 100.0 | 158 | 100.0 |

Source table(s): 4.4-2

Table 7.7-2-3: Noninferiority test on responder rate for the PP sample

| | | | | | | |
|---|-------|------|-------|---------|---------|--------|
| GEL | 70/80 | 89.7 | -0.10 | -0.0526 | -0.0562 | 0.1613 |
| DROP | 76/80 | 95.0 | | | | |
| oo | | | | | | |

Source table(s): 4.5-2

Evaluation of responders at Visit 5 (day 15)

Because the responder rate is 100% for both treatment groups, no computation/estimation is possible. See tables 4.6-1 and 4.6.2 of Appendix 1.

Description of responders for the sub-group

As previously defined (see paragraph 6.4), the description of the subset of patients with Cellularity and/or Flare degree greater than zero at Visi 3 (day 1) is summarized in the below table.

Table 7.7-2-4: Grade of Flare and Cellularity for the patients showing severity degree greater than zero at Visit 3

| | | | | | | | GEL (N=22/80) | DROP (N=27/80) | ALL (N=49/160) |
|---|------------|----|-------|----|-------|----|------------------|-------------------|-------------------|
| Visit | | n | % | n | % | n | % | | |
| oo | | | | | | | | | |
| Flare | V4 - (n %) | | | | | | | | |
| | None | 17 | 77.3 | 24 | 88.9 | 41 | 83.7 | | |
| | Faint | 5 | 22.7 | 3 | 11.1 | 8 | 16.3 | | |
| | Total | 22 | 100.0 | 27 | 100.0 | 49 | 100.0 | | |
| | V5 - (n %) | | | | | | | | |
| | None | 22 | 100.0 | 27 | 100.0 | 49 | 100.0 | | |
| | Total | 22 | 100.0 | 27 | 100.0 | 49 | 100.0 | | |
| Cellularity | V4 - (n %) | | | | | | | | |
| | 0 grade | 6 | 60.0 | 7 | 77.8 | 13 | 68.4 | | |
| | 0.5 grade | 4 | 40.0 | 2 | 22.2 | 6 | 31.6 | | |
| | Total | 10 | 100.0 | 9 | 100.0 | 19 | 100.0 | | |
| | V5 - (n %) | | | | | | | | |
| | 0 grade | 10 | 100.0 | 8 | 88.9 | 18 | 94.7 | | |
| | 0.5 grade | 0 | 0.0 | 1 | 11.1 | 1 | 5.3 | | |
| | Total | 10 | 100.0 | 9 | 100.0 | 19 | 100.0 | | |

Source table(s): 4.7-1, 4.8-1

Evaluation of antibiotic efficacy at Visit 3 (Day 1)

No patients have showed microbial load. See Table 4.9 of Appendix 1.

Evaluation of Intra-Ocular Pressure (IOP)

The values of IOP for treated and no-treated eye are within the normal range (12-22 mmHg) except for patient 200101 who showed an IOP of 34 mmHg on the treated eye at Visit 3 (day 1) decreased to 16 mmHg at Visit 4 (day 7).

The point estimation description and change with values at Visit 1 (screening) of IOP are reported in the Tables 6.1-1 and 6.1-2 and the difference between treated vs no-treated eye at Table 6.1-3 of Appendix 1.

Evaluation of Visual acuity

No relevant difference in the study and between treatment groups are present.
See Table 6.3-1 of Appendix 1.

Evaluation of Ophthalmoscopy test

No relevant difference in the study and between treatment groups are present. See the table below.

Table 7.7-2-5: Abnormality frequency recorded with Ophthalmoscopy test

| Variable | Visit | GEL (N=85) | | DROP (N=83) | | ALL (N=168) | |
|----------|-------|---------------|-----|----------------|-----|----------------|-----|
| | | n | % | n | % | n | % |
| Vitreous | V1 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| | V3 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| | V4 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| | V5 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Retina | V1 | 2 | 2.4 | 2 | 2.4 | 4 | 2.4 |
| | V3 | 2 | 2.4 | 2 | 2.5 | 4 | 2.5 |
| | V4 | 2 | 2.5 | 2 | 2.5 | 4 | 2.5 |
| | V5 | 2 | 2.5 | 2 | 2.5 | 4 | 2.5 |
| Macula | V1 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| | V3 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| | V4 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| | V5 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Choroid | V1 | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 |
| | V3 | 0 | 0.0 | 2 | 2.5 | 2 | 1.2 |
| | V4 | 0 | 0.0 | 2 | 2.5 | 2 | 1.3 |
| | V5 | 0 | 0.0 | 2 | 2.5 | 2 | 1.3 |

Source table(s): from 6.2-2-1 to 6.2-5-2

Evaluation of Ophthalmoscopy test

No relevant difference in the study and between treatment groups are present. See the table below.

Table 7.7-2-6 (1 of 2): Ocular inflammation signs/symptoms change from Visit 3 (day 1)

| | GEL (N=85) | | DROP (N=83) | | ALL (N=168) | |
|---------------------------------|------------|-------|-------------|-------|-------------|-------|
| Visit | n | % | n | % | n | % |
| Anterior chamber flare | | | | | | |
| V4 | | | | | | |
| decreased | 17 | 20.7 | 24 | 29.3 | 41 | 25.0 |
| unchanged | 65 | 79.3 | 58 | 70.7 | 123 | 75.0 |
| increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| total | 82 | 100.0 | 82 | 100.0 | 164 | 100.0 |
| V5 | | | | | | |
| decreased | 21 | 25.9 | 27 | 33.3 | 48 | 29.6 |
| unchanged | 60 | 74.1 | 54 | 66.7 | 114 | 70.4 |
| increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| total | 81 | 100.0 | 81 | 100.0 | 162 | 100.0 |
| Anterior chamber cells | | | | | | |
| V4 | | | | | | |
| decreased | 6 | 7.3 | 4 | 4.9 | 10 | 6.1 |
| unchanged | 76 | 92.7 | 77 | 93.9 | 153 | 93.3 |
| increased | 0 | 0.0 | 1 | 1.2 | 1 | 0.6 |
| total | 82 | 100.0 | 82 | 100.0 | 164 | 100.0 |
| V5 | | | | | | |
| decreased | 7 | 8.6 | 4 | 4.9 | 11 | 6.8 |
| unchanged | 74 | 91.4 | 77 | 95.1 | 151 | 93.2 |
| increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| total | 81 | 100.0 | 81 | 100.0 | 162 | 100.0 |
| Conjunctival hyperemia | | | | | | |
| V4 | | | | | | |
| decreased | 6 | 7.3 | 7 | 8.5 | 13 | 7.9 |
| unchanged | 74 | 90.2 | 75 | 91.5 | 149 | 90.9 |
| increased | 2 | 2.4 | 0 | 0.0 | 2 | 1.2 |
| total | 82 | 100.0 | 82 | 100.0 | 164 | 100.0 |
| V5 | | | | | | |
| decreased | 7 | 8.6 | 7 | 8.6 | 14 | 8.6 |
| unchanged | 72 | 88.9 | 73 | 90.1 | 145 | 89.5 |
| increased | 2 | 2.5 | 1 | 1.2 | 3 | 1.9 |
| total | 81 | 100.0 | 81 | 100.0 | 162 | 100.0 |
| Lid edema | | | | | | |
| V4 | | | | | | |
| decreased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| unchanged | 82 | 100.0 | 82 | 100.0 | 164 | 100.0 |
| increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| total | 82 | 100.0 | 82 | 100.0 | 164 | 100.0 |
| V5 | | | | | | |
| decreased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| unchanged | 81 | 100.0 | 81 | 100.0 | 162 | 100.0 |
| increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| total | 81 | 100.0 | 81 | 100.0 | 162 | 100.0 |
| Corneal edema | | | | | | |
| V4 | | | | | | |
| decreased | 3 | 3.7 | 1 | 1.2 | 4 | 2.4 |
| unchanged | 79 | 96.3 | 81 | 98.8 | 160 | 97.6 |
| increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| total | 82 | 100.0 | 82 | 100.0 | 164 | 100.0 |
| V5 | | | | | | |
| decreased | 2 | 2.5 | 1 | 1.2 | 3 | 1.9 |
| unchanged | 79 | 97.5 | 80 | 98.8 | 159 | 98.1 |
| increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| total | 81 | 100.0 | 81 | 100.0 | 162 | 100.0 |
| Ocular discomfort - Pain | | | | | | |
| V4 | | | | | | |
| decreased | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| unchanged | 81 | 98.8 | 81 | 98.8 | 162 | 98.8 |
| increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| total | 82 | 100.0 | 82 | 100.0 | 164 | 100.0 |
| V5 | | | | | | |
| decreased | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| unchanged | 80 | 98.8 | 80 | 98.8 | 160 | 98.8 |
| increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| total | 81 | 100.0 | 81 | 100.0 | 162 | 100.0 |

Table 7.7-2-6 (2 of 2): Ocular inflammation signs/symptoms change from Visit 3 (day 1)

| | GEL (N=85) | | DROP (N=83) | | ALL (N=168) | |
|--|------------|-------|-------------|-------|-------------|-------|
| Visit | n | % | n | % | n | % |
| Ocular discomfort - Photophobia | | | | | | |
| V4 | | | | | | |
| decreased | 7 | 8.5 | 4 | 4.9 | 11 | 6.7 |
| unchanged | 74 | 90.2 | 77 | 93.9 | 151 | 92.1 |
| increased | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| total | 82 | 100.0 | 82 | 100.0 | 164 | 100.0 |
| V5 | | | | | | |
| decreased | 8 | 9.9 | 3 | 3.7 | 11 | 6.8 |
| unchanged | 72 | 88.9 | 77 | 95.1 | 149 | 92.0 |
| increased | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| total | 81 | 100.0 | 81 | 100.0 | 162 | 100.0 |
| Tearing | | | | | | |
| V4 | | | | | | |
| decreased | 7 | 8.5 | 4 | 4.9 | 11 | 6.7 |
| unchanged | 73 | 89.0 | 76 | 92.7 | 149 | 90.9 |
| increased | 2 | 2.4 | 2 | 2.4 | 4 | 2.4 |
| total | 82 | 100.0 | 82 | 100.0 | 164 | 100.0 |
| V5 | | | | | | |
| decreased | 9 | 11.1 | 4 | 4.9 | 13 | 8.0 |
| unchanged | 68 | 84.0 | 75 | 92.6 | 143 | 88.3 |
| increased | 4 | 4.9 | 2 | 2.5 | 6 | 3.7 |
| total | 81 | 100.0 | 81 | 100.0 | 162 | 100.0 |

Source table(s): from 6.4-2 to 6.4-9

Evaluation of Global tolerability

No relevant difference in the study and between treatment groups are present. See the table below.

Table 7.7-2-7 (1 of 2): Global tolerability by Investigator change from Visit 3 (day 1)

| | GEL (N=85) | | DROP (N=83) | | ALL (N=168) | |
|-----------------------|------------|-------|-------------|-------|-------------|-------|
| Visit | n | % | n | % | n | % |
| Burning | | | | | | |
| V4 | | | | | | |
| decreased | 6 | 7.3 | 4 | 4.9 | 10 | 6.1 |
| unchanged | 76 | 92.7 | 77 | 93.9 | 153 | 93.3 |
| increased | 0 | 0.0 | 1 | 1.2 | 1 | 0.6 |
| total | 82 | 100.0 | 82 | 100.0 | 164 | 100.0 |
| V5 | | | | | | |
| decreased | 7 | 8.6 | 4 | 4.9 | 11 | 6.8 |
| unchanged | 74 | 91.4 | 77 | 95.1 | 151 | 93.2 |
| increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| total | 81 | 100.0 | 81 | 100.0 | 162 | 100.0 |
| Stinging | | | | | | |
| V4 | | | | | | |
| decreased | 4 | 4.9 | 3 | 3.7 | 7 | 4.3 |
| unchanged | 77 | 93.9 | 76 | 93.8 | 153 | 93.9 |
| increased | 1 | 1.2 | 2 | 2.5 | 3 | 1.8 |
| total | 82 | 100.0 | 81 | 100.0 | 163 | 100.0 |
| V5 | | | | | | |
| decreased | 5 | 6.3 | 3 | 3.8 | 8 | 5.0 |
| unchanged | 73 | 91.3 | 76 | 95.0 | 149 | 93.1 |
| increased | 2 | 2.5 | 1 | 1.3 | 3 | 1.9 |
| total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| Blurred vision | | | | | | |
| V4 | | | | | | |
| decreased | 1 | 1.2 | 0 | 0.0 | 1 | 0.6 |
| unchanged | 78 | 95.1 | 79 | 97.5 | 157 | 96.3 |
| increased | 3 | 3.7 | 2 | 2.5 | 5 | 3.1 |
| total | 82 | 100.0 | 81 | 100.0 | 163 | 100.0 |
| V5 | | | | | | |
| decreased | 2 | 2.5 | 0 | 0.0 | 2 | 1.3 |
| unchanged | 76 | 95.0 | 77 | 96.3 | 153 | 95.6 |
| increased | 2 | 2.5 | 3 | 3.8 | 5 | 3.1 |
| total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |

Table 7.7-2-7 (2 of 2): Global tolerability by Investigator change from Visit 3 (day 1)

| | GEL (N=85) | | DROP (N=83) | | ALL (N=168) | |
|---------------------------------------|------------|-------|-------------|-------|-------------|-------|
| Visit | n | % | n | % | n | % |
| Global subjective tolerability | | | | | | |
| | | | | | | |
| V4 decreased | 1 | 1.2 | 0 | 0.0 | 1 | 0.6 |
| unchanged | 81 | 98.8 | 81 | 100.0 | 162 | 99.4 |
| increased | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| total | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| V5 decreased | 1 | 1.3 | 0 | 0.0 | 1 | 0.6 |
| unchanged | 78 | 97.5 | 79 | 98.8 | 157 | 98.1 |
| increased | 1 | 1.3 | 1 | 1.3 | 2 | 1.3 |
| total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |

Source table(s): from 6.5-2 to 6.5-5

Concomitant medications

Table 7.7-2-8: Main ATC class of concomitant medications (numeric descending order)

| ATC Class | GEL (N=85) | DROP (N=83) | ALL (N=168) | |
|--|---------------|----------------|----------------|------|
| Preferred term | n | % | n | % |
| Subjects with at least one concomitant medication | 61 | 71.8 | 55 | 66.3 |
| | 116 | 69.0 | | |
| CARDIOVASCULAR SYSTEM | 49 | 57.6 | 46 | 55.4 |
| BLOOD AND BLOOD FORMING ORGANS | 16 | 18.8 | 17 | 20.5 |
| NERVOUS SYSTEM | 16 | 18.8 | 8 | 9.6 |
| ALIMENTARY TRACT AND METABOLISM | 14 | 16.5 | 8 | 9.6 |
| SENSORY ORGANS | 8 | 9.4 | 8 | 9.6 |
| SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES | 6 | 7.1 | 10 | 12.0 |
| ANTIINFECTIVES FOR SYSTEMIC USE | 7 | 8.2 | 6 | 7.2 |
| MUSCULO-SKELETAL SYSTEM | 7 | 8.2 | 3 | 3.6 |
| GENITO URINARY SYSTEM AND SEX HORMONES | 2 | 2.4 | 3 | 3.6 |
| ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS | 1 | 1.2 | 1 | 1.2 |
| RESPIRATORY SYSTEM | . | . | 2 | 2.4 |
| VARIOUS | 1 | 1.2 | 1 | 1.2 |
| ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENT | . | . | 1 | 1.2 |

Source table(s): 5.1

Adverse events

The total number of patients with adverse events is 10, 4 for GEL group (4.7%) and 6 for DROP group (7.2%) while the total number of patients with SAE is 2, all for DROP group.
Only 1 patient, of GEL group, showed a relation with study drug.

In the table below, the frequency of patients with AE.

Table 7.7-2-8: Summary of all Adverse Events by MedDRA System Organ Class (numeric descending order)

| System Organ Class Preferred term | GEL (N=85) | | DROP (N=83) | | ALL (N=168) | |
|--|---------------|-----|----------------|-----|----------------|-----|
| | n | % | n | % | n | % |
| Subjects with at least one event | 4 | 4.7 | 6 | 7.2 | 10 | 6.0 |
| Eye disorders | 1 | 1.2 | 3 | 3.6 | 4 | 2.4 |
| Investigations | 3 | 3.5 | . | . | 3 | 1.8 |
| Gastrointestinal disorders | 1 | 1.2 | . | . | 1 | 0.6 |
| Immune system disorders | . | . | 1 | 1.2 | 1 | 0.6 |
| Infections and infestations | . | . | 1 | 1.2 | 1 | 0.6 |
| Injury, poisoning and procedural complications | 1 | 1.2 | . | . | 1 | 0.6 |
| Vascular disorders | . | . | 1 | 1.2 | 1 | 0.6 |

For the details, see Tables from 6.6-1 to 6.6-5 of Appendix 1 and Listing 17 of Appendix 2.

APPENDIX 1: Statistical tables

| | Page |
|--|-----------|
| Study flow-chart | 5 |
| 1. Patient accountability..... | 6 |
| Table 1.1 Number of subjects treated (randomized), completed the study and discontinued by center - Randomized sample..... | 7 |
| Table 1.2 Summary of Subjects disposition - Randomized sample..... | 8 |
| Table 1.3 Number of subjects with protocol violations - Randomized sample..... | 10 |
| Table 1.4 Summary of patient sets disposition - Randomized sample..... | 11 |
| Table 1.5 Patient accountability - Summary of demographic characteristics, by population and study drug..... | 12 |
| Table 1.6 Summary of time interval (days) among visits - Safety sample..... | 13 |
| Table 1.7 Summary of time interval (days) between post-surgery visits vs. surgery visit - Safety sample..... | 14 |
| 2. Demographic and baseline characteristics..... | 15 |
| Table 2.1 Demographic characteristics and pregnancy test at study entry - Safety sample..... | 16 |
| Table 2.2 Clinical tests at study entry - Safety sample..... | 17 |
| Table 2.3 Ophthalmoscopy test at study entry - Safety sample..... | 20 |
| Table 2.4 General medical history before surgery, by primary system organ class and preferred term Safety sample..... | 21 |
| Table 2.5 Ophthalmic medical history before surgery, by primary system organ class and preferred term - Safety sample..... | 25 |
| Table 2.6 Antibiotics before surgery, by primary system organ class and preferred term Safety sample..... | 29 |
| 3. Evaluation at surgery day..... | 30 |
| Table 3.1 Examinations at day of surgery - Safety sample..... | 31 |
| Table 3.2 Surgery problems - Safety sample..... | 32 |
| Table 3.3-1 Mydriatic and Antibiotic drugs at surgery - Safety sample..... | 33 |
| Table 3.3-2 Study treatment administration during the study - Safety sample..... | 34 |
| Table 3.4 Evaluation of ocular inflammation signs/symptoms at surgery - Safety sample..... | 35 |
| 4. Efficacy evaluation after surgery..... | 37 |
| Table 4.1-1 Slit lamp evaluation during the study - Frequency of test execution - ITT sample..... | 38 |
| Table 4.1-2 Slit lamp evaluation during the study - Frequency of test execution - PP sample..... | 39 |
| Table 4.2-1 Slit lamp evaluation during the study - Grade of CELLULARITY of the treated eye during the study and change from Day 1 - ITT sample..... | 40 |

APPENDIX 1 (cont.d)

| | Page |
|--|-------------|
| Table 4.2-2 Slit lamp evaluation during the study - Grade of CELLULARITY of the treated eye during the study and change from Day 1 - PP sample..... | 41 |
| Table 4.3-1 Slit lamp evaluation during the study - Grade of FLARE of the treated eye during the study and change from Day 1- ITT sample..... | 42 |
| Table 4.3-2 Slit lamp evaluation during the study - Grade of FLARE of the treated eye during the study and change from Day 1 - PP sample..... | 43 |
| Table 4.4-1 Slit lamp evaluation during the study - Summary of study drug response at endpoint stratified by sex, age and centre - ITT sample..... | 44 |
| Table 4.4-2 Slit lamp evaluation during the study - Summary of study drug response at endpoint stratified by sex, age and centre - PP sample..... | 46 |
| Table 4.5-1 Slit lamp evaluation during the study Analysis to test the noninferiority of GEL group (test) vs. EYE DROPS group (control) on occurrence of full-responder at endpoint - ITT sample..... | 48 |
| Table 4.5-2 Slit lamp evaluation during the study Analysis to test the noninferiority of GEL group (test) vs. EYE DROPS group (control) on occurrence of full-responder at endpoint - PP sample..... | 49 |
| Table 4.6-1 Slit lamp evaluation during the study Analysis to test the noninferiority of GEL group (test) vs. EYE DROPS group (control) on occurrence of full-responder at Visit 5 (Day 15) - ITT sample..... | 50 |
| Table 4.6-2 Slit lamp evaluation during the study Analysis to test the noninferiority of GEL group (test) vs. EYE DROPS group (control) on occurrence of full-responder at Visit 5 (Day 15) - PP sample..... | 51 |
| Table 4.7-1 Slit lamp evaluation during the study Grade of FLARE of the treated eye during the study only for patients showing degree greater than zero at Visit 3 (Day 7) - ITT sample..... | 52 |
| Table 4.7-2 Slit lamp evaluation during the study Grade of FLARE of the treated eye during the study only for patients showing degree greater than zero at Visit 3 (Day 7) - PP sample..... | 53 |
| Table 4.8-1 Slit lamp evaluation during the study Grade of CELLULARITY of the treated eye during the study only for patients showing degree greater than zero at Visit 3 (Day 7) - ITT sample..... | 54 |
| Table 4.8-2 Slit lamp evaluation during the study Grade of CELLULARITY of the treated eye during the study only for patients showing degree greater than zero at Visit 3 (Day 7) - PP sample..... | 55 |
| Table 4.9 Microbial load during the study - Frequency of test execution - ITT sample..... | 56 |
| 5. Medications..... | 57 |
| Table 5.1 Number of patients with concomitant medications, by ATC therapeutic class and preferred term - Safety sample..... | 58 |
| Table 5.2 Number of patients assuming study drugs during the study - Safety sample..... | 59 |

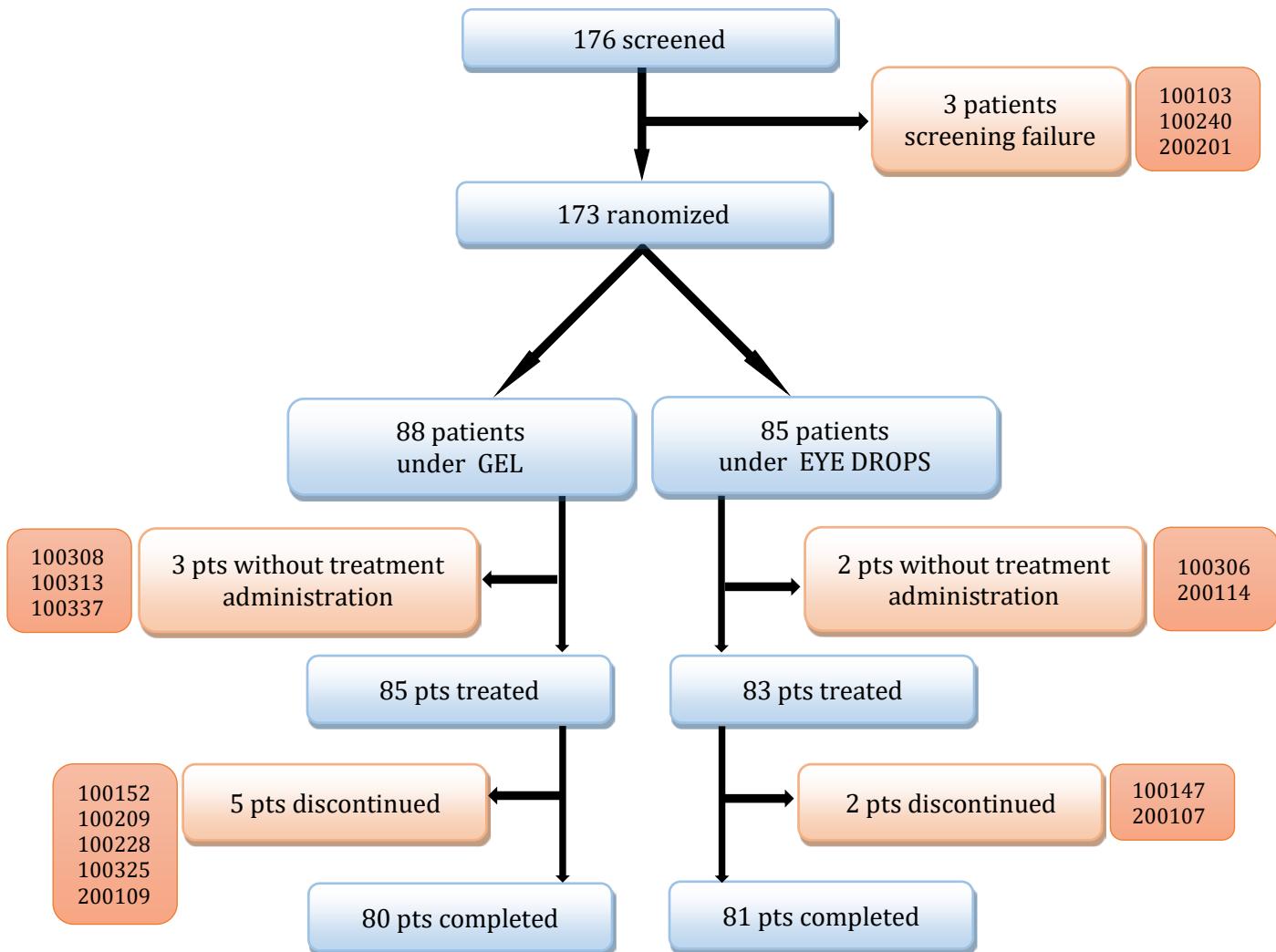
APPENDIX 1 (cont.d)

| | Page |
|---------------|---|
| 6. | Safety evaluation..... |
| | 65 |
| 6.1 | Intra Ocular Pressure..... |
| Table 6.1-1 | Intra ocular pressure on treated eye - Point estimate of IOP and change from baseline visite - Safety sample..... |
| | 67 |
| Table 6.1-2 | Intra ocular pressure on non-treated eye - Point estimate of IOP and change from baseline visite - Safety sample..... |
| | 69 |
| Table 6.1-3 | Intra ocular pressure - Point estimate of the difference between Treated vs. Non-treated eye - Safety sample..... |
| | 70 |
| 6.2 | Ophthalmoscopy test..... |
| Table 6.2-1 | Ophthalmoscopy test during the study - Frequency of test execution during the study - Safety sample..... |
| | 72 |
| Table 6.2-2-1 | Ophthalmoscopy test during the study - Frequency for Vitreous- Safety sample..... |
| | 73 |
| Table 6.2-2-2 | Ophthalmoscopy test during the study - Shift table for Vitreous - Safety sample..... |
| | 74 |
| Table 6.2-3-1 | Ophthalmoscopy test during the study - Frequency for Retina - Safety sample..... |
| | 75 |
| Table 6.2-3-2 | Ophthalmoscopy test during the study - Shift table for Retina - Safety sample..... |
| | 76 |
| Table 6.2-4-1 | Ophthalmoscopy test during the study - Frequency for Macula - Safety sample..... |
| | 77 |
| Table 6.2-4-2 | Ophthalmoscopy test during the study - Shift table for Macula- Safety sample..... |
| | 78 |
| Table 6.2-5-1 | Ophthalmoscopy test during the study - Frequency for Choroid- Safety sample..... |
| | 79 |
| Table 6.2-5-2 | Ophthalmoscopy test during the study - Shift table for Choroid - Safety sample..... |
| | 80 |
| 6.3 | Visual acuity..... |
| Table 6.3-1 | Visual acuity during the study for the treated eye - Safety sample..... |
| | 82 |
| 6.4 | Ocular inflammation evalution..... |
| Table 6.4-1 | Signs/Symptoms of ocular inflammation evaluation during the study - Frequency of test execution - Safety sample..... |
| | 84 |
| Table 6.4-2 | Evaluation of ocular inflammation signs/symptoms during the study - Anterior chamber flare - Safety sample..... |
| | 85 |
| Table 6.4-3 | Evaluation of ocular inflammation signs/symptoms during the study - Anterior chamber cells - Safety sample..... |
| | 86 |
| Table 6.4-4 | Evaluation of ocular inflammation signs/symptoms during the study - Conjunctival hyperemia - Safety sample..... |
| | 87 |

APPENDIX 1 (cont.d)

| | Page | |
|--------------|--|------------|
| Table 6.4-5 | Evaluation of ocular inflammation signs/symptoms during the study - Lid edema - Safety sample..... | 88 |
| Table 6.4-6 | Evaluation of ocular inflammation signs/symptoms during the study - Corneal edema - Safety sample..... | 89 |
| Table 6.4-7 | Evaluation of ocular inflammation signs/symptoms during the study - Ocular discomfort - Pain - Safety sample..... | 90 |
| Table 6.4-8 | Evaluation of ocular inflammation signs/symptoms during the study - Ocular discomfort - Photophobia - Safety sample..... | 91 |
| Table 6.4-9 | Evaluation of ocular inflammation signs/symptoms during the study - Ocular discomfort - Tearing - Safety sample..... | 92 |
| Table 6.4-10 | Evaluation of ocular inflammation signs/symptoms during the study - Total score - Safety sample..... | 93 |
| 6.5 | Global tolerability..... | 94 |
| Table 6.5-1 | Evaluation of global tolerability by the investigator during the study - Frequency of test execution - Safety sample..... | 95 |
| Table 6.5-2 | Evaluation of global tolerability by the investigator during the study - Burning - Safety sample..... | 96 |
| Table 6.5-3 | Evaluation of global tolerability by the investigator during the study - Stinging - Safety sample..... | 97 |
| Table 6.5-4 | Evaluation of global tolerability by the investigator during the study - Blurred vision Safety sample..... | 98 |
| Table 6.5-5 | Evaluation of global tolerability by the investigator during the study - Global subjective tolerability - Safety sample..... | 99 |
| 6.6 | Adverse events..... | 100 |
| Table 6.6-1 | Overview of Adverse Events - Safety sample..... | 101 |
| Table 6.6-2 | Summary of all Adverse Events by MedDRA System Organ Class and Preferred Term - Safety sample..... | 102 |
| Table 6.6-3 | Summary of Serious Adverse Events, by MedDRA System Organ Class and Preferred Term - Safety sample..... | 104 |
| Table 6.6-4 | Summary of Related Adverse Events, by MedDRA System Organ Class and Preferred Term - Safety sample..... | 105 |
| Table 6.6-5 | Summary of Adverse Events leading to discontinuation, by MedDRA System Organ Class and Preferred Term - Safety sample..... | 106 |

Study flow-chart



GEL: NETILDEX 3mg/mL / 1mg/mL ophthalmic gel

EYE DROPS: NETILDEX 3mg/mL / 1mg/mL eye drops solutions

1. Patient accountability

**Table 1.1 (1 of 1): Number of subjects treated (randomized), completed the study and discontinued by center
Randomized sample**

| Center Code | Name | GEL (N=85) | | | | | | EYE DROPS (N=83) | | | | | | ALL (N=168) | | | | | | | | | | | | | | |
|----------------|-----------------|------------|----|-------|--------|------|---|------------------|----|-------|-----|------|---|-------------|-----|-------|----------|------|---|-----|---|---|--------|---|---|----------|---|---|
| | | Trt | | | Compl. | | | Discont. | | | Trt | | | Compl. | | | Discont. | | | Trt | | | Compl. | | | Discont. | | |
| | | n | n | % | n | n | % | n | n | % | n | n | % | n | n | % | n | n | % | n | n | % | n | n | % | n | n | % |
| 1001 | IT01 - Rome | 28 | 27 | 96.4 | 1 | 3.6 | | 27 | 26 | 96.3 | 1 | 3.7 | | 55 | 53 | 96.4 | 2 | 3.6 | | | | | | | | | | |
| 1002 | IT02 - Florence | 22 | 20 | 90.9 | 2 | 9.1 | | 22 | 22 | 100.0 | . | . | | 44 | 42 | 95.5 | 2 | 4.5 | | | | | | | | | | |
| 1003 | IT03 - Milan | 26 | 25 | 96.2 | 1 | 3.8 | | 26 | 26 | 100.0 | . | . | | 52 | 51 | 98.1 | 1 | 1.9 | | | | | | | | | | |
| 2001 | DE01 - Potsdam | 7 | 6 | 85.7 | 1 | 14.3 | | 7 | 6 | 85.7 | 1 | 14.3 | | 14 | 12 | 85.7 | 2 | 14.3 | | | | | | | | | | |
| 2002 | DE02 - Würzburg | 2 | 2 | 100.0 | . | . | | 1 | 1 | 100.0 | . | . | | 3 | 3 | 100.0 | . | . | | | | | | | | | | |
| Total | | 85 | 80 | 94.1 | 5 | 5.9 | | 83 | 81 | 97.6 | 2 | 2.4 | | 168 | 161 | 95.8 | 7 | 4.2 | | | | | | | | | | |

SAS program: P03_T01_01.sas - SAS dataset(s): RAND, EOS

Note: - Trt=treated
- percents of Completed and Discontinued are computed on treated subjects of correspondent row

Table 1.2 (1 of 1): Summary of Subjects disposition
Randomized sample

| | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Randomized | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Completed study | 80 | 94.1 | 81 | 97.6 | 161 | 95.8 |
| Discontinued | 5 | 5.9 | 2 | 2.4 | 7 | 4.2 |
| <hr/> | | | | | | |
| Main reason for study discontinuation - (n %) | | | | | | |
| Withdrawal of consent/Patient choice | 4 | 80.0 | 1 | 50.0 | 5 | 71.4 |
| Adverse event | 1 | 20.0 | 1 | 50.0 | 2 | 28.6 |
| Major complications during cataract surgery | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Lack of efficacy | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Protocol violation, including disallowed conc | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Investigator considers it not in the patient' | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Sponsor terminates the study | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 5 | 100.0 | 2 | 100.0 | 7 | 100.0 |

SAS program: P03_T01_02.sas - SAS dataset(s): RAND, EOS

Listing of patients discontinued

Subj.

code Reason for discontinuation

GEL

100152 Withdrawal of consent/Patient choice
100209 Withdrawal of consent/Patient choice
100228 Withdrawal of consent/Patient choice
100325 Withdrawal of consent/Patient choice
200109 Adverse event

EYE DROPS

100147 Withdrawal of consent/Patient choice
200107 Adverse event

Table 1.3 (1 of 1): Number of subjects with protocol violations
Randomized sample

| Protocol violation | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--|---------------|-----|---------------------|---|----------------|-----|
| | n | % | n | % | n | % |
| Any protocol violation | 2 | 2.4 | . | . | 2 | 1.2 |
| Eclusion criteria 5 (type 2 diabetse mellitus) | 1 | 1.2 | . | . | 1 | 0.6 |
| Inclusion criteria 2 (age <40yrs) | 1 | 1.2 | . | . | 1 | 0.6 |

Source: on-line editing

Listing of subjects with protocol violations

| Age | | | |
|---------|----------|--------|--|
| Pat. ID | ID (yrs) | Sex | Violation reported on database |
| 100302 | 61 | male | Patient suffering of type 2 Diabetes Mellitus (exclusion criteria 5) |
| 100348 | 38 | female | Patient age < 40 years old (inclusion criteria 2) |

Table 1.4 (1 of 1): Summary of patient sets disposition
Randomized sample

| No. of patients | GEL (N=88) | | EYE DROPS (N=85) | | ALL (N=173) | |
|--------------------------|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Screened | 176 100.0 | | | | | |
| Screening failure (1) | 3 1.7 | | | | | |
| Randomized | 88 | 100.0 | 85 | 100.0 | 173 | 100.0 |
| Non treated patients (2) | 3 | 3.4 | 2 | 2.4 | 5 | 2.9 |
| Treated patients | 85 | 96.6 | 83 | 97.6 | 168 | 97.1 |
| Treated patients | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Safety population | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| ITT population (3) | 80 | 94.1 | 80 | 96.4 | 160 | 95.2 |
| PP population (4) | 78 | 91.8 | 80 | 96.4 | 158 | 64.0 |

Source: on-line editing

Listing of not regular patients regarding the disposition and details on presence of study drug assumption and SLIT lamp execution

| Subj. cde | Study drug | Reason | -Study drug- | | | -----SLIT lamp----- | | | | |
|--------------|------------|---|--------------|-----|-----|---------------------|-----|-----|-----|----|
| | | | V2 | V3 | V4 | V1 | V3 | V4 | V5 | V6 |
| (1) 100103 | No treated | Screening failure | | | | | | | | |
| 100240 | No treated | Screening failure | | | | | | | | |
| 200201 | No treated | Screening failure | | | | | | | | |
| (2) 100306 | EYE DROPS | no study drug intake | | | | | | | | |
| 100308 | GEL | no study drug intake | | | | | | | | |
| 100313 | GEL | no study drug intake | | | | | | | | |
| 100337 | GEL | no study drug intake | | | | | | | | |
| 200104 | EYE DROPS | no study drug intake | | | | | | | | |
| (3) 100209 | GEL | no study drug intake at baseline & endpoint | Yes | | | Yes | | | | |
| 100228 | GEL | no study drug intake at endpoint | Yes | Yes | No | Yes | Yes | Yes | | |
| 100325 | GEL | no study drug intake at baseline & endpoint | Yes | | | Yes | | | | |
| 200109 | GEL | no study drug intake at endpoint | Yes | Yes | No | Yes | Yes | Yes | | |
| 100147 | EYE DROPS | no study drug intake at baseline | Yes | No | Yes | Yes | Yes | Yes | | |
| 100326 | EYE DROPS | no study drug intake at baseline | Yes | No | Yes | Yes | Yes | Yes | Yes | |
| 200107 | EYE DROPS | no study drug intake at baseline | Yes | No | | Yes | Yes | | | |
| (4) 100302 | GEL | protocol violation (type 2 Diabetes Mellitus) | Yes | Yes | Yes | Yes | Yes | Yes | Yes | |
| 100348 | GEL | protocol violation (age < 40 years old) | Yes | Yes | Yes | Yes | Yes | Yes | Yes | |

Missing value when premature discontinued patient

Table 1.5 (1 of 1): Patient accountability - Summary of demographic characteristics, by population and study drug

| Variable | Safety sample | | | ITT sample | | | PP sample | | |
|--------------------------|---------------|---------------------|----------------|---------------|---------------------|----------------|---------------|---------------------|----------------|
| | GEL (N=85) | EYE DROPS (N=83) | ALL (N=168) | GEL (N=80) | EYE DROPS (N=80) | ALL (N=160) | GEL (N=78) | EYE DROPS (N=80) | ALL (N=158) |
| Age (years) | | | | | | | | | |
| N | 85 | 83 | 168 | 80 | 80 | 160 | 78 | 80 | 158 |
| Mean | 72.2 | 73.2 | 72.7 | 71.8 | 73.7 | 72.8 | 72.4 | 73.7 | 73.0 |
| SD | 8.8 | 8.3 | 8.6 | 8.9 | 7.6 | 8.3 | 8.0 | 7.6 | 7.8 |
| Median | 74.0 | 74.0 | 74.0 | 73.0 | 74.0 | 74.0 | 73.5 | 74.0 | 74.0 |
| Range | 38.0 | 89.0 | 48.0 89.0 | 38.0 | 89.0 | 38.0 89.0 | 48.0 | 89.0 | 51.0 89.0 |
| Age class - (n %) | | | | | | | | | |
| <=65 | 17 | 20.0 | 14 16.9 | 31 18.5 | 17 21.3 | 12 15.0 | 29 18.1 | 15 19.2 | 12 15.0 |
| 66-74 | 34 | 40.0 | 29 34.9 | 63 37.5 | 33 41.3 | 29 36.3 | 62 38.8 | 33 42.3 | 29 36.3 |
| >=75 | 34 | 40.0 | 40 48.2 | 74 44.0 | 30 37.5 | 39 48.8 | 69 43.1 | 30 38.5 | 39 48.8 |
| Total | 85 | 100.0 | 83 100.0 | 168 100.0 | 80 100.0 | 80 100.0 | 160 100.0 | 78 100.0 | 80 100.0 |
| Sex - (n %) | | | | | | | | | |
| Male | 37 | 43.5 | 26 31.3 | 63 37.5 | 37 46.3 | 24 30.0 | 61 38.1 | 36 46.2 | 24 30.0 |
| Female | 48 | 56.5 | 57 68.7 | 105 62.5 | 43 53.8 | 56 70.0 | 99 61.9 | 42 53.8 | 56 70.0 |
| Total | 85 | 100.0 | 83 100.0 | 168 100.0 | 80 100.0 | 80 100.0 | 160 100.0 | 78 100.0 | 80 100.0 |

SAS program: P03_01_05.sas - SAS dataset(s): _Populations

**Table 1.6 (1 of 1): Summary of time interval (days) among visits
Safety sample**

| Interval among visits | GEL (N=85) | EYE DROPS (N=83) | ALL (N=168) |
|--|---------------|---------------------|----------------|
| V1 (screening) vs. V2 (surgery)* | | | |
| N | 85 | 83 | 168 |
| Mean | 6.1 | 5.6 | 5.8 |
| SD | 5.6 | 1.1 | 4.0 |
| Median | 6.0 | 6.0 | 6.0 |
| Range | 2.0 56.0 | 1.0 8.0 | 1.0 56.0 |
| V2 (surgery) vs. V3 (day 1) | | | |
| N | 83 | 83 | 166 |
| Mean | 1.0 | 1.0 | 1.0 |
| SD | 0.1 | 0.1 | 0.1 |
| Median | 1.0 | 1.0 | 1.0 |
| Range | 1.0 2.0 | 1.0 2.0 | 1.0 2.0 |
| V3 (day 1) vs. V4 (day 7) | | | |
| N | 83 | 82 | 165 |
| Mean | 6.1 | 6.2 | 6.1 |
| SD | 1.3 | 2.0 | 1.7 |
| Median | 6.0 | 6.0 | 6.0 |
| Range | 4.0 15.0 | 5.0 22.0 | 4.0 22.0 |
| V4 (day 7) vs. V5 (day 15 - End of treatment) | | | |
| N | 81 | 81 | 162 |
| Mean | 7.4 | 7.1 | 7.2 |
| SD | 1.3 | 0.9 | 1.1 |
| Median | 7.0 | 7.0 | 7.0 |
| Range | 0.0 13.0 | 5.0 9.0 | 0.0 13.0 |
| V5 (day 15) vs. V6 (follow-up) | | | |
| N | 80 | 81 | 161 |
| Mean | 45.9 | 46.3 | 46.1 |
| SD | 6.9 | 4.3 | 5.7 |
| Median | 47.0 | 47.0 | 47.0 |
| Range | 10.0 77.0 | 13.0 54.0 | 10.0 77.0 |

SAS program: P03_01_06.sas - SAS dataset(s): RAND, VISIT

* Patient 100205 with V1 date=14DEC2017 and V2 date=08FEB2018

**Table 1.7 (1 of 1): Summary of time interval (days) between post-surgery visits vs. surgery visit
Safety sample**

| Interval among visits | GEL (N=85) | EYE DROPS (N=83) | ALL (N=168) |
|---|---------------|---------------------|----------------|
| V2 (surgery) vs. V3 (day 1) | | | |
| N | 83 | 83 | 166 |
| Mean | 1.0 | 1.0 | 1.0 |
| SD | 0.1 | 0.1 | 0.1 |
| Median | 1.0 | 1.0 | 1.0 |
| Range | 1.0 2.0 | 1.0 2.0 | 1.0 2.0 |
| V3 (day 1) vs. V4 (day 7) | | | |
| N | 83 | 82 | 165 |
| Mean | 7.1 | 7.2 | 7.1 |
| SD | 1.3 | 1.9 | 1.7 |
| Median | 7.0 | 7.0 | 7.0 |
| Range | 6.0 16.0 | 6.0 23.0 | 6.0 23.0 |
| V4 (day 15) vs. V5 (day 15 - End of treatment) | | | |
| N | 81 | 81 | 162 |
| Mean | 14.4 | 14.1 | 14.3 |
| SD | 1.1 | 0.9 | 1.0 |
| Median | 14.0 | 14.0 | 14.0 |
| Range | 13.0 20.0 | 12.0 16.0 | 12.0 20.0 |
| V5 (day 15) vs. V6 (follow-up) | | | |
| N | 80 | 81 | 161 |
| Mean | 60.3 | 60.4 | 60.3 |
| SD | 6.7 | 4.2 | 5.6 |
| Median | 61.0 | 61.0 | 61.0 |
| Range | 25.0 91.0 | 27.0 70.0 | 25.0 91.0 |

SAS program: P03_01_07.sas - SAS dataset(s): RAND,VISIT

2. Demographic and baseline characteristics

**Table 2.1 (1 of 1): Demographic characteristics and pregnancy test at study entry
Safety sample**

| Variable | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | | Difference between study drugs | 95% CI of difference |
|----------------------------------|---------------|-------|---------------------|-------|----------------|-------|--------------------------------------|-------------------------|
| | n | % | n | % | n | % | | |
| Age (years)* | | | | | | | -0.9931 | -3.6090 1.6229 |
| N | 85 | | 83 | | 168 | | | |
| Mean | 72.2 | | 73.2 | | 72.7 | | | |
| SD | 8.8 | | 8.3 | | 8.6 | | | |
| Median | 74.0 | | 74.0 | | 74.0 | | | |
| Range | 38.0 | 89.0 | 48.0 | 89.0 | 38.0 | 89.0 | | |
| Age frequency - (n %) | | | | | | | | |
| <=65 | 16 | 18.8 | 15 | 18.1 | 31 | 18.5 | | |
| 66-74 | 37 | 43.5 | 28 | 33.7 | 65 | 38.7 | | |
| >=75 | 32 | 37.6 | 40 | 48.2 | 72 | 42.9 | | |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 | | |
| Sex - (n %) | | | | | | | 12.2000 | -2.3100 26.7200 |
| Male | 37 | 43.5 | 26 | 31.3 | 63 | 37.5 | | |
| Female | 48 | 56.5 | 57 | 68.7 | 105 | 62.5 | | |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 | | |
| Race - (n %) | | | | | | | | |
| White | 84 | 98.8 | 81 | 97.6 | 165 | 98.2 | | |
| Black | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 | | |
| Asian | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | | |
| Middle-eastern | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | | |
| Other | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | | |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 | | |
| Pregnancy - (n %) | | | | | | | | |
| No | 1 | 1.2 | 0 | 0.0 | 1 | 0.6 | | |
| Yes | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | | |
| NA (male) | 36 | 42.4 | 26 | 31.3 | 62 | 36.9 | | |
| NA (out of childbearing age) | 48 | 56.5 | 56 | 67.5 | 104 | 61.9 | | |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 | | |
| Result of pregnancy test - (n %) | | | | | | | | |
| Positive | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | | |
| Negative | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | | |
| Total | 0 | 100.0 | 0 | 100.0 | 0 | 100.0 | | |

SAS program: P03_T02_01.sas - SAS dataset(s): RAND,DEMOGRAPHY,PREGNANCY

* Age was computed from date of birth and date of informed consent

**Table 2.2 (1 of 3): Clinical tests at study entry
Safety sample**

| Variable | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| AMSLER test performed - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| If YES, result of AMSLER test - (n %) | | | | | | |
| Positive | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Negative | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| OCT test performed - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| If YES, result of OCT test - (n %) | | | | | | |
| Positive | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Negative | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Visual acuity - Treated eye (fraction) | | | | | | |
| N | 85 | | 83 | | 168 | |
| Mean | 0.5 | | 0.5 | | 0.5 | |
| SD | 0.2 | | 0.2 | | 0.2 | |
| Median | 0.5 | | 0.5 | | 0.5 | |
| Range | 0.0 | 1.0 | 0.0 | 1.0 | 0.0 | 1.0 |
| Visual acuity - Non-treated eye (fraction) | | | | | | |
| N | 85 | | 83 | | 168 | |
| Mean | 0.7 | | 0.6 | | 0.7 | |
| SD | 0.3 | | 0.3 | | 0.3 | |
| Median | 0.7 | | 0.7 | | 0.7 | |
| Range | 0.0 | 1.3 | 0.0 | 1.0 | 0.0 | 1.3 |
| Visual acuity - Difference between Treated and Non-treated eye (fraction) | | | | | | |
| N | 85 | | 83 | | 168 | |
| Mean | -0.2 | | -0.1 | | -0.1 | |
| SD | 0.3 | | 0.4 | | 0.4 | |
| Median | -0.2 | | -0.2 | | -0.2 | |
| Range | -0.8 | 0.7 | -0.8 | 0.7 | -0.8 | 0.7 |

**Table 2.2 (2 of 3): Clinical tests at study entry
Safety sample**

| Variable | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|------|---------------------|------|----------------|------|
| | n | % | n | % | n | % |
| Intra Ocular Pressure (mmHg) | | | | | | |
| Treated eye (mmHg) | | | | | | |
| N | 85 | | 83 | | 168 | |
| Mean | 15.3 | | 15.4 | | 15.4 | |
| SD | 1.9 | | 1.8 | | 1.9 | |
| Median | 16.0 | | 16.0 | | 16.0 | |
| Range | 10.0 | 19.0 | 10.0 | 20.0 | 10.0 | 20.0 |
| Non-treated eye (mmHg) | | | | | | |
| N | 85 | | 83 | | 168 | |
| Mean | 15.1 | | 15.2 | | 15.1 | |
| SD | 2.0 | | 1.7 | | 1.8 | |
| Median | 15.0 | | 15.0 | | 15.0 | |
| Range | 10.0 | 20.0 | 10.0 | 19.0 | 10.0 | 20.0 |
| Difference between Treated and Non-treated eye (mmHg) | | | | | | |
| N | 85 | | 83 | | 168 | |
| Mean | 0.2 | | 0.2 | | 0.2 | |
| SD | 1.4 | | 1.4 | | 1.4 | |
| Median | 0.0 | | 0.0 | | 0.0 | |
| Range | -4.0 | 6.0 | -5.0 | 4.0 | -5.0 | 6.0 |

**Table 2.2 (3 of 3): Clinical tests at study entry
Safety sample**

| Variable | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Slit lamp examination performed - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Grade of cellularity - (n %) | | | | | | |
| 0 grade | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| 0.5 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 1 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 2 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 3 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 4 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Grade of flare - (n %) | | | | | | |
| None | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Faint | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Marked | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Intense | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |

SAS program: P03_T02_02.sas - SAS dataset(s): RAND, INTRA_PRES, SLIT, SURGERY, AMSLER, OCT, VISUAL_SCREEN

**Table 2.3 (1 of 1): Ophthalmoscopy test at study entry
Safety sample**

| Variable | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|-------------------------------|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Test performed - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Vitreous - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Abnormal | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Retina - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 83 | 97.6 | 81 | 97.6 | 164 | 97.6 |
| Abnormal | 2 | 2.4 | 2 | 2.4 | 4 | 2.4 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Macula - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Abnormal | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Choroid - (n %) | | | | | | |
| Not done | 0 | 0.0 | 1 | 1.2 | 1 | 0.6 |
| Normal | 84 | 98.8 | 80 | 96.4 | 164 | 97.6 |
| Abnormal | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |

SAS program: P03_T02_03.sas - SAS dataset(s): NameFile: RAND,OPHTHALMOSCOPY

**Table 2.4 (1 of 4): General medical history before surgery, by primary system organ class and preferred term
Safety sample**

| System Organ Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--|---------------|------|---------------------|------|----------------|------|
| | n | % | n | % | n | % |
| Subjects with at least one event | 59 | 69.4 | 61 | 73.5 | 120 | 71.4 |
| Blood and lymphatic system disorders | . | . | 1 | 1.2 | 1 | 0.6 |
| Systemic mastocytosis | . | . | 1 | 1.2 | 1 | 0.6 |
| Cardiac disorders | 9 | 10.6 | 8 | 9.6 | 17 | 10.1 |
| Angina pectoris | 1 | 1.2 | . | . | 1 | 0.6 |
| Arrhythmia | 2 | 2.4 | . | . | 2 | 1.2 |
| Atrial fibrillation | 2 | 2.4 | 1 | 1.2 | 3 | 1.8 |
| Bradycardia | . | . | 1 | 1.2 | 1 | 0.6 |
| Cardiac disorder | 1 | 1.2 | 3 | 3.6 | 4 | 2.4 |
| Cardiac failure chronic | 1 | 1.2 | . | . | 1 | 0.6 |
| Cardiovascular disorder | . | . | 1 | 1.2 | 1 | 0.6 |
| Extrasystoles | 1 | 1.2 | . | . | 1 | 0.6 |
| Ischaemic cardiomyopathy | . | . | 1 | 1.2 | 1 | 0.6 |
| Myocardial ischaemia | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| Ear and labyrinth disorders | 2 | 2.4 | . | . | 2 | 1.2 |
| Hypoacusis | 1 | 1.2 | . | . | 1 | 0.6 |
| Vertigo labyrinthine | 1 | 1.2 | . | . | 1 | 0.6 |
| Endocrine disorders | 5 | 5.9 | 9 | 10.8 | 14 | 8.3 |
| Hypothyroidism | 5 | 5.9 | 7 | 8.4 | 12 | 7.1 |
| Thyroid mass | . | . | 1 | 1.2 | 1 | 0.6 |
| Thyroiditis | . | . | 1 | 1.2 | 1 | 0.6 |
| Gastrointestinal disorders | 6 | 7.1 | 8 | 9.6 | 14 | 8.3 |
| Abdominal pain upper | 1 | 1.2 | . | . | 1 | 0.6 |
| Constipation | 1 | 1.2 | . | . | 1 | 0.6 |
| Diverticulum | . | . | 1 | 1.2 | 1 | 0.6 |
| Diverticulum intestinal | 1 | 1.2 | . | . | 1 | 0.6 |
| Gastritis | . | . | 1 | 1.2 | 1 | 0.6 |
| Gastrooesophageal reflux disease | 2 | 2.4 | 5 | 6.0 | 7 | 4.2 |
| Hiatus hernia | . | . | 1 | 1.2 | 1 | 0.6 |
| Inguinal hernia | 1 | 1.2 | . | . | 1 | 0.6 |
| General disorders and administration site conditions | 2 | 2.4 | . | . | 2 | 1.2 |
| Hyperplasia | 1 | 1.2 | . | . | 1 | 0.6 |
| Pain | 1 | 1.2 | . | . | 1 | 0.6 |

**Table 2.4 (2 of 4): General medical history before surgery, by primary system organ class and preferred term
Safety sample**

| System Organ Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|------|---------------------|------|----------------|------|
| | n | % | n | % | n | % |
| Hepatobiliary disorders | 1 | 1.2 | . | . | 1 | 0.6 |
| Cholelithiasis | 1 | 1.2 | . | . | 1 | 0.6 |
| Immune system disorders | 1 | 1.2 | 5 | 6.0 | 6 | 3.6 |
| Allergy to arthropod sting | . | . | 1 | 1.2 | 1 | 0.6 |
| Allergy to venom | . | . | 1 | 1.2 | 1 | 0.6 |
| Drug hypersensitivity | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| Food allergy | . | . | 1 | 1.2 | 1 | 0.6 |
| Seasonal allergy | . | . | 1 | 1.2 | 1 | 0.6 |
| Infections and infestations | 1 | 1.2 | . | . | 1 | 0.6 |
| Lyme disease | 1 | 1.2 | . | . | 1 | 0.6 |
| Investigations | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| Blood cholesterol increased | . | . | 1 | 1.2 | 1 | 0.6 |
| Blood uric acid increased | 1 | 1.2 | . | . | 1 | 0.6 |
| Metabolism and nutrition disorders | 15 | 17.6 | 16 | 19.3 | 31 | 18.5 |
| Diabetes mellitus | 2 | 2.4 | 2 | 2.4 | 4 | 2.4 |
| Dyslipidaemia | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 |
| Fluid retention | . | . | 1 | 1.2 | 1 | 0.6 |
| Gout | 2 | 2.4 | . | . | 2 | 1.2 |
| Hypercholesterolaemia | 11 | 12.9 | 11 | 13.3 | 22 | 13.1 |
| Hyperlipidaemia | 1 | 1.2 | . | . | 1 | 0.6 |
| Hyperuricaemia | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 |
| Type 2 diabetes mellitus | 1 | 1.2 | . | . | 1 | 0.6 |
| Vitamin B12 deficiency | . | . | 1 | 1.2 | 1 | 0.6 |
| Musculoskeletal and connective tissue disorders | 8 | 9.4 | 5 | 6.0 | 13 | 7.7 |
| Osteoarthritis | . | . | 1 | 1.2 | 1 | 0.6 |
| Osteopenia | 1 | 1.2 | . | . | 1 | 0.6 |
| Osteoporosis | 6 | 7.1 | 4 | 4.8 | 10 | 6.0 |
| Psoriatic arthropathy | . | . | 1 | 1.2 | 1 | 0.6 |
| Scleroderma | 1 | 1.2 | . | . | 1 | 0.6 |

**Table 2.4 (3 of 4): General medical history before surgery, by primary system organ class and preferred term
Safety sample**

| System Organ Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|------|---------------------|-----|----------------|-----|
| | n | % | n | % | n | % |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 1.2 | 5 | 6.0 | 6 | 3.6 |
| Colon cancer | 1 | 1.2 | . | . | 1 | 0.6 |
| Lung neoplasm malignant | 1 | 1.2 | . | . | 1 | 0.6 |
| Malignant melanoma | . | . | 1 | 1.2 | 1 | 0.6 |
| Meningioma | . | . | 1 | 1.2 | 1 | 0.6 |
| Monoclonal gammopathy | . | . | 1 | 1.2 | 1 | 0.6 |
| Prostate cancer | . | . | 1 | 1.2 | 1 | 0.6 |
| Prostatic adenoma | . | . | 1 | 1.2 | 1 | 0.6 |
| Nervous system disorders | 2 | 2.4 | 2 | 2.4 | 4 | 2.4 |
| Ischaemic stroke | . | . | 1 | 1.2 | 1 | 0.6 |
| Neuropathy peripheral | . | . | 1 | 1.2 | 1 | 0.6 |
| Polyneuropathy | 1 | 1.2 | . | . | 1 | 0.6 |
| Transient ischaemic attack | 1 | 1.2 | . | . | 1 | 0.6 |
| Psychiatric disorders | 9 | 10.6 | 4 | 4.8 | 13 | 7.7 |
| Anxiety | 5 | 5.9 | 1 | 1.2 | 6 | 3.6 |
| Depression | 2 | 2.4 | 1 | 1.2 | 3 | 1.8 |
| Insomnia | 2 | 2.4 | 2 | 2.4 | 4 | 2.4 |
| Renal and urinary disorders | 2 | 2.4 | . | . | 2 | 1.2 |
| Bladder discomfort | 1 | 1.2 | . | . | 1 | 0.6 |
| Nephropathy | 1 | 1.2 | . | . | 1 | 0.6 |
| Reproductive system and breast disorders | 1 | 1.2 | 3 | 3.6 | 4 | 2.4 |
| Benign prostatic hyperplasia | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 |
| Prostatomegaly | . | . | 1 | 1.2 | 1 | 0.6 |
| Respiratory, thoracic and mediastinal disorders | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 |
| Asthma | . | . | 1 | 1.2 | 1 | 0.6 |
| Chronic obstructive pulmonary disease | . | . | 1 | 1.2 | 1 | 0.6 |
| Pulmonary hypertension | 1 | 1.2 | . | . | 1 | 0.6 |
| Social circumstances | 1 | 1.2 | . | . | 1 | 0.6 |
| Menopause | 1 | 1.2 | . | . | 1 | 0.6 |

**Table 2.4 (4 of 4): General medical history before surgery, by primary system organ class and preferred term
Safety sample**

| System Organ Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--------------------------------------|---------------|------|---------------------|------|----------------|------|
| | n | % | n | % | n | % |
| Surgical and medical procedures | | | | | | |
| Adenoidectomy | 1 | 1.2 | . | . | 1 | 0.6 |
| Angioplasty | . | . | 1 | 1.2 | 1 | 0.6 |
| Appendicectomy | 2 | 2.4 | 1 | 1.2 | 3 | 1.8 |
| Breast conserving surgery | 2 | 2.4 | . | . | 2 | 1.2 |
| Carotid endarterectomy | 1 | 1.2 | . | . | 1 | 0.6 |
| Cholecystectomy | . | . | 1 | 1.2 | 1 | 0.6 |
| Hernia repair | . | . | 1 | 1.2 | 1 | 0.6 |
| Hysterectomy | . | . | 1 | 1.2 | 1 | 0.6 |
| Hysterosalpingo-oophorectomy | 1 | 1.2 | . | . | 1 | 0.6 |
| Nephrectomy | . | . | 1 | 1.2 | 1 | 0.6 |
| Prostatectomy | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 |
| Renal tumour excision | 1 | 1.2 | . | . | 1 | 0.6 |
| Rotator cuff repair | . | . | 1 | 1.2 | 1 | 0.6 |
| Thyroidectomy | 1 | 1.2 | . | . | 1 | 0.6 |
| Tonsillectomy | 1 | 1.2 | . | . | 1 | 0.6 |
| Vascular disorders | 44 | 51.8 | 40 | 48.2 | 84 | 50.0 |
| Angiopathy | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| Hypertension | 43 | 50.6 | 40 | 48.2 | 83 | 49.4 |
| Thrombophlebitis | . | . | 1 | 1.2 | 1 | 0.6 |
| Thrombophlebitis superficial | 1 | 1.2 | . | . | 1 | 0.6 |

SAS program: P03_T02_04.sas - SAS dataset(s): RAND,MEDHIS_COD

A subject with multiple occurrences of an event is counted only once in the respective category.
Arranged alphabetically by System Organ Class

**Table 2.5 (1 of 1): Ophthalmic medical history before surgery, by primary system organ class and preferred term
Safety sample**

| System Organ Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | | Difference between treatment | 95% CI of difference |
|---|---------------|------|---------------------|------|----------------|------|------------------------------------|-------------------------|
| | n | % | n | % | n | % | | |
| Subjects with at least one event | 18 | 21.2 | 17 | 20.5 | 35 | 20.8 | 6.9 | -0.12 0.13 |
| Eye disorders | | | | | | | | |
| Amblyopia | 10 | 11.8 | 11 | 13.3 | 21 | 12.5 | | |
| Cataract | 1 | 1.2 | . | . | 1 | 0.6 | | |
| Dry eye | 9 | 10.6 | 10 | 12.0 | 19 | 11.3 | | |
| Myopia | . | . | 2 | 2.4 | 2 | 1.2 | | |
| Retinal detachment | . | . | 1 | 1.2 | 1 | 0.6 | | |
| Retinal infarction | 1 | 1.2 | . | . | 1 | 0.6 | | |
| Vitreomacular interface abnormal | . | . | 1 | 1.2 | 1 | 0.6 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | | | | | | |
| Eye naevus | 1 | 1.2 | . | . | 1 | 0.6 | | |
| Surgical and medical procedures | | | | | | | | |
| Cataract operation | 9 | 10.6 | 9 | 10.8 | 18 | 10.7 | | |
| Lens capsulotomy | . | . | 1 | 1.2 | 1 | 0.6 | | |
| Retinal laser coagulation | . | . | 1 | 1.2 | 1 | 0.6 | | |
| Strabismus correction | . | . | 1 | 1.2 | 1 | 0.6 | | |

SAS program: P03_T02_05.sas - SAS dataset(s): RAND,OPHHIS_COD

A subject with multiple occurrences of an event is counted only once in the respective category.
Arranged alphabetically by System Organ Class

Listing of patients with Ophthalmic medical history before surgery - Safety sample (1 of 3)

| Sbj | Study | Age | Date of | | | |
|--------|-------|--------|---------|--------------------------------|-----------|---------|
| Code | drug | Sex | (year) | Reported term | diagnosis | Ongoing |
| 100201 | GEL | Female | 80 | LEFT EYE CATARACT SURGERY | 26JAN2017 | NO |
| . | . | . | | RIGHT EYE CATARACT | 2015 | YES |
| 100202 | DROPS | Female | 70 | LEFT EYE CATARACT | 2016 | YES |
| . | . | . | | RIGHT EYE CATARACT | 2016 | YES |
| 100203 | DROPS | Female | 76 | LEFT EYE CATARACT SURGERY | 2013 | NO |
| . | . | . | | LEFT EYE YAG LASER CAPSULOTOMY | 2015 | NO |
| . | . | . | | RIGHT EYE CATARACT | 2015 | YES |
| 100204 | GEL | Male | 71 | RIGHT EYE CATARACT | 2016 | YES |
| 100205 | GEL | Male | 75 | LEFT EYE CATARACT | 2016 | YES |
| . | . | . | | RIGHT EYE CATARACT | 2016 | YES |
| 100206 | DROPS | Female | 81 | DRY EYE SYNDROME | 2016 | YES |
| . | . | . | | LEFT EYE CATARACT SURGERY | 19OCT2017 | NO |
| . | . | . | | RIGHT EYE CATARACT | 2016 | YES |
| 100207 | DROPS | Female | 65 | HIGH MYOPIA | 1967 | YES |
| . | . | . | | LEFT EYE CATARACT | 2015 | YES |
| . | . | . | | RIGHT EYE CATARACT | 2015 | YES |
| 100208 | GEL | Female | 79 | LEFT EYE CATARACT SURGERY | JAN2016 | NO |
| 100209 | GEL | Female | 77 | LEFT EYE CATARACT | 2016 | YES |
| . | . | . | | RIGHT EYE CATARACT | 2016 | YES |
| 100210 | DROPS | Female | 70 | LEFT EYE CATARACT SURGERY | 12OCT2017 | NO |
| . | . | . | | RIGHT EYE CATARACT | 2016 | YES |
| 100211 | GEL | Male | 67 | LEFT EYE CATARACT | 2016 | YES |
| . | . | . | | RIGHT EYE CATARACT | 2016 | YES |
| 100212 | DROPS | Female | 82 | LEFT EYE CATARACT SURGERY | 2016 | YES |
| . | . | . | | RIGHT EYE CATARACT SURGERY | SEP2017 | YES |
| 100213 | DROPS | Female | 81 | DRY EYE SYNDROME | 2008 | YES |
| . | . | . | | LEFT EYE CATARACT | 2016 | YES |
| . | . | . | | RIGHT EYE CATARACT SURGERY | 9FEB2017 | YES |

Listing of patients with Ophthalmic medical history before surgery - Safety sample (2 of 3)

| Sbj | Study | Age | Date of | | | |
|--------|-------|--------|---------|--------------------------------|-----------|---------|
| Code | drug | Sex | (year) | Reported term | diagnosis | Ongoing |
| 100214 | DROPS | Female | 77 | LEFT EYE CATARACT | 2016 | YES |
| . | . | . | . | RIGHT EYE-VITREORETINAL INTERF | 2017 | YES |
| | | | | ACE SYNDROME | | |
| 100215 | GEL | Female | 83 | LEFT EYE CATARACT | 2007 | YES |
| 100216 | GEL | Female | 74 | LEFT EYE CATARACT | | YES |
| . | . | . | . | RIGHT EYE CATARACT SURGERY | APR2016 | NO |
| 100217 | DROPS | Female | 72 | LEFT EYE CATARACT SURGERY | 2NOV2017 | NO |
| . | . | . | . | RIGHT EYE CATARACT | 2016 | YES |
| 100218 | DROPS | Male | 72 | LEFT EYE CATARACT SURGERY | 23NOV2017 | NO |
| 100219 | GEL | Female | 83 | CHOROIDEAL NEVUS LEFT EYE | JAN2018 | YES |
| 100220 | GEL | Male | 64 | RIGHT EYE CATARACT SURGERY | 14DEC2017 | NO |
| 100222 | DROPS | Female | 76 | RIGHT EYE CATARACT SURGERY | 2016 | NO |
| 100228 | GEL | Female | 68 | LEFT EYE CATARACT SURGERY | 2016 | NO |
| 100233 | GEL | Female | 72 | RIGHT EYE CATARACT SURGERY | 2017 | NO |
| 100234 | GEL | Female | 73 | LEFT EYE CATARACT SURGERY | 2017 | NO |
| 100235 | DROPS | Male | 64 | LEFT EYE CATARACT SURGERY | 2010 | NO |
| 100236 | DROPS | Female | 70 | LEFT EYE RETINAL LASER BARRAGE | 2016 | NO |
| 100237 | DROPS | Male | 73 | STRABISMUS SURGERY | 1990 | NO |
| 100238 | GEL | Male | 78 | LEFT EYE CATARACT SURGERY | 2014 | NO |
| 100240 | | Female | 72 | RIGHT EYE CATARACT SURGERY | 2017 | NO |
| 100242 | GEL | Female | 67 | CATARACT-BOTH EYES | 2017 | YES |
| 100243 | DROPS | Male | 74 | CATARACT-BOTH EYES | 2017 | YES |

Listing of patients with Ophthalmic medical history before surgery - Safety sample (3 of 3)

| Sbj | Study | Age | | Date of | | |
|--------|-------|--------|--------|---|-------------------------------------|----------------|
| Code | drug | Sex | (year) | Reported term | diagnosis | Ongoing |
| 100244 | GEL | Female | 66 | LEFT EYE CATARACT SURGERY | JAN2018 | NO |
| 100245 | DROPS | Female | 69 | CATARACT-BOTH EYES | 2017 | YES |
| 100305 | DROPS | Female | 85 | PREVIOUS INFARCTION OD | 2016 | NO |
| 100348 | GEL | Female | 38 | MILD AMBLYOPIA | | YES |
| 200203 | GEL | Male | 66 | OD: CATARACT OD: RHEGMATOGENOUS RETINAL DETACHMENT OS: RHEGMATOGENOUS PERIPHERAL RETINAL DETACHMENT | 10MAR2014 10MAR2014 25AUG2016 | NO NO NO |

SAS program: L03_List_05.sas - SAS dataset(s): RAND,DEMOGRAPHY,MEDHIS_COD,OPHHIS_COD

**Table 2.6 (1 of 1): Antibiotics before surgery, by primary system organ class and preferred term
Safety sample**

| Therapeutic area Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | | Difference between treatment | 95% CI of difference |
|---------------------------------------|---------------|------|---------------------|------|----------------|------|------------------------------------|-------------------------|
| | n | % | n | % | n | % | | |
| Subjects with at least one medication | 46 | 54.1 | 47 | 56.6 | 93 | 55.4 | 2.51 | -12.52 17.54 |
| SENSORY ORGANS | 46 | 54.1 | 47 | 56.6 | 93 | 55.4 | | |
| LEVOFLOXACIN | 20 | 23.5 | 20 | 24.1 | 40 | 23.8 | | |
| NETILDEX | 2 | 2.4 | 3 | 3.6 | 5 | 3.0 | | |
| NETILMICIN | 24 | 28.2 | 24 | 28.9 | 48 | 28.6 | | |

SAS program: P03_T02_06.sas - SAS dataset(s): RAND,ANTI_BEFORE_COD

A subject with multiple occurrences of an event is counted only once in the respective category.
Arranged alphabetically by Therapeutic Area

3. Evaluation at surgery day

**Table 3.1 (1 of 1): Examinations at day of surgery
Safety sample**

| Variable | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Eye involved - (n %) | | | | | | |
| Left eye | 45 | 52.9 | 40 | 48.2 | 85 | 50.6 |
| Right eye | 40 | 47.1 | 43 | 51.8 | 83 | 49.4 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Bromfenac treatment before surgery - (n %) | | | | | | |
| No | 1 | 1.2 | 0 | 0.0 | 1 | 0.6 |
| Yes | 84 | 98.8 | 83 | 100.0 | 167 | 99.4 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| 3 days before surgery - (n %) | | | | | | |
| No | 2 | 2.4 | 0 | 0.0 | 2 | 1.2 |
| Yes | 83 | 97.6 | 83 | 100.0 | 166 | 98.8 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| 2 days before surgery - (n %) | | | | | | |
| No | 2 | 2.4 | 2 | 2.4 | 4 | 2.4 |
| Yes | 83 | 97.6 | 81 | 97.6 | 164 | 97.6 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| 1 day before surgery - (n %) | | | | | | |
| No | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 |
| Yes | 84 | 98.8 | 81 | 97.6 | 165 | 98.2 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Ocular surface sterilization - (n %) | | | | | | |
| No | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| Yes | 84 | 98.8 | 82 | 98.8 | 166 | 98.8 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |

SAS program: P03_T03_01.sas - SAS dataset(s): RAND,SURGERY,BROM_TRT

**Table 3.2 (1 of 1): Surgery problems
Safety sample**

| Variable | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Any procedural issue/problem (not AE) occurred during cataract surgery - (n %) | | | | | | |
| No | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Yes | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Patient suffered from any surgical complication - (n %) | | | | | | |
| No | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Yes | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |

SAS program: P03_T03_02.sas - SAS dataset(s): RAND,SURGERY

**Table 3.3-1 (1 of 1): Mydriatic and Antibiotic drugs at surgery
Safety sample**

| Variable | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Mydriatic drugs during surgery - (n %) | | | | | | |
| No | 2 | 2.4 | 0 | 0.0 | 2 | 1.2 |
| Yes | 83 | 97.6 | 83 | 100.0 | 166 | 98.8 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Antibiotics after surgery - (n %) | | | | | | |
| No | 66 | 77.6 | 61 | 73.5 | 127 | 75.6 |
| Yes | 19 | 22.4 | 22 | 26.5 | 41 | 24.4 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |

SAS program: P03_T03_03_01.sas - SAS dataset(s): RAND,MYDRIATIC_YN,ANTI_AFTER_YN

**Table 3.3-2 (1 of 1): Study treatment administration during the study
Safety sample**

| Visit | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| V2 (surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 3 | 3.6 | 3 | 1.8 |
| Yes | 83 | 100.0 | 80 | 96.4 | 163 | 98.2 |
| Total | 83 | 100.0 | 83 | 100.0 | 166 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| No | 3 | 3.6 | 0 | 0.0 | 3 | 1.8 |
| Yes | 80 | 96.4 | 82 | 100.0 | 162 | 98.2 |
| Total | 83 | 100.0 | 82 | 100.0 | 165 | 100.0 |

SAS program: P03_T03_03_02.sas - SAS dataset(s): RAND,TREATMENT

**Table 3.4 (1 of 2): Evaluation of ocular inflammation signs/symptoms at surgery
Safety sample**

| Variable | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---------------------------------------|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Evaluation performed - (n %) | | | | | | |
| No | 7 | 8.2 | 7 | 8.4 | 14 | 8.3 |
| Yes | 78 | 91.8 | 76 | 91.6 | 154 | 91.7 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Anterior chamber flare - (n %) | | | | | | |
| None | 57 | 73.1 | 54 | 71.1 | 111 | 72.1 |
| Faint | 21 | 26.9 | 22 | 28.9 | 43 | 27.9 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Marked | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Intense | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |
| Anterior chamber cells - (n %) | | | | | | |
| None | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |
| Mild | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Severe | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |
| Conjunctival hyperemia - (n %) | | | | | | |
| None | 71 | 91.0 | 73 | 96.1 | 144 | 93.5 |
| Mild | 7 | 9.0 | 3 | 3.9 | 10 | 6.5 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Severe | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |
| Lid edema - (n %) | | | | | | |
| None | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |
| Mild | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Severe | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |
| Corneal edema - (n %) | | | | | | |
| None | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |
| Mild | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Severe | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |

**Table 3.4 (2 of 2): Evaluation of ocular inflammation signs/symptoms at surgery
Safety sample**

| Variable | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Ocular discomfort: pain - (n %) | | | | | | |
| None | 77 | 98.7 | 76 | 100.0 | 153 | 99.4 |
| Mild | 1 | 1.3 | 0 | 0.0 | 1 | 0.6 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Severe | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |
| Ocular discomfort: photophobia - (n %) | | | | | | |
| None | 69 | 88.5 | 67 | 88.2 | 136 | 88.3 |
| Mild | 9 | 11.5 | 9 | 11.8 | 18 | 11.7 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Severe | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |
| Ocular discomfort: tearing - (n %) | | | | | | |
| None | 68 | 87.2 | 69 | 90.8 | 137 | 89.0 |
| Mild | 10 | 12.8 | 7 | 9.2 | 17 | 11.0 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Severe | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 78 | 100.0 | 76 | 100.0 | 154 | 100.0 |
| Total score | | | | | | |
| N | 78 | | 76 | | 154 | |
| Mean | 0.6 | | 0.5 | | 0.6 | |
| SD | 0.8 | | 0.8 | | 0.8 | |
| Median | 0.0 | | 0.0 | | 0.0 | |
| Range | 0.0 | 3.0 | 0.0 | 3.0 | 0.0 | 3.0 |

SAS program: P03_T03_04.sas - SAS dataset(s):

4. Efficacy evaluation after surgery

**Table 4.1-1 (1 of 1): Slit lamp evaluation during the study - Frequency of test execution
ITT sample**

| Visit | GEL (N=80) | | EYE DROPS (N=80) | | ALL (N=160) | |
|--|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| V1 (before surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| Total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| Total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| Total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| Total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 79 | 100.0 | 79 | 98.8 | 158 | 99.4 |
| Total | 79 | 100.0 | 80 | 100.0 | 159 | 100.0 |

SAS program: P03_T04_01_01.sas - SAS dataset(s): RAND,SLIT

Note: patient 100152 with no measurement of SLIT lamp at Visit 6

**Table 4.1-2 (1 of 1): Slit lamp evaluation during the study - Frequency of test execution
PP sample**

| Visit | GEL (N=78) | | EYE DROPS (N=80) | | ALL (N=158) | |
|--|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| V1 (before surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 78 | 100.0 | 80 | 100.0 | 158 | 100.0 |
| Total | 78 | 100.0 | 80 | 100.0 | 158 | 100.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 78 | 100.0 | 80 | 100.0 | 158 | 100.0 |
| Total | 78 | 100.0 | 80 | 100.0 | 158 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 78 | 100.0 | 80 | 100.0 | 158 | 100.0 |
| Total | 78 | 100.0 | 80 | 100.0 | 158 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 78 | 100.0 | 80 | 100.0 | 158 | 100.0 |
| Total | 78 | 100.0 | 80 | 100.0 | 158 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 77 | 100.0 | 79 | 98.8 | 156 | 99.4 |
| Total | 77 | 100.0 | 80 | 100.0 | 157 | 100.0 |

SAS program: P03_T04_01_02.sas - SAS dataset(s): RAND,SLIT

**Table 4.2-1 (1 of 1): Slit lamp evaluation during the study - Grade of CELLULARITY of the treated eye during the study and change from Day 1
ITT sample**

| Visit | GEL (N=80) | | | EYE DROPS (N=80) | | | ALL (N=160) | | | |
|---|-------------------|-------|-------------------|------------------|-------------------|-------|-------------------|-----------|-------------------|-------|
| | Change from Day 1 | | Change from Day 1 | | Change from Day 1 | | Change from Day 1 | | Change from Day 1 | |
| | n | % | n | % | n | % | n | % | n | % |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | |
| 0 grade | 70 | 87.5 | | | 71 | 88.8 | | | 141 | 88.1 |
| 0.5 grade | 6 | 7.5 | | | 4 | 5.0 | | | 10 | 6.3 |
| 1 grade | 4 | 5.0 | | | 5 | 6.3 | | | 9 | 5.6 |
| 2 grade | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| 3 grade | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| 4 grade | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 80 | 100.0 | | | 80 | 100.0 | | | 160 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | |
| 0 (<1 cell) | 75 | 93.8 | decreased | 8 | 10.0 | 78 | 97.5 | decreased | 8 | 10.0 |
| 0.5 (1-5 cells) | 5 | 6.3 | unchanged | 71 | 88.8 | 2 | 2.5 | unchanged | 72 | 90.0 |
| 1 (6-15 cells) | 0 | 0.0 | increased | 1 | 1.3 | 0 | 0.0 | increased | 0 | 0.0 |
| 2 (16-25 cells) | 0 | 0.0 | total | 80 | 100.0 | 0 | 0.0 | total | 80 | 100.0 |
| 3 (26-50 cells) | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| 4 (>50 cells) | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 80 | 100.0 | | | 80 | 100.0 | | | 160 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | |
| 0 (<1 cell) | 80 | 100.0 | decreased | 10 | 12.5 | 79 | 98.8 | decreased | 9 | 11.3 |
| 0.5 (1-5 cells) | 0 | 0.0 | unchanged | 70 | 87.5 | 1 | 1.3 | unchanged | 71 | 88.8 |
| 1 (6-15 cells) | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 |
| 2 (16-25 cells) | 0 | 0.0 | total | 80 | 100.0 | 0 | 0.0 | total | 80 | 100.0 |
| 3 (26-50 cells) | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| 4 (>50 cells) | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 80 | 100.0 | | | 80 | 100.0 | | | 160 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | | | | | |
| 0 (<1 cell) | 77 | 97.5 | decreased | 10 | 12.5 | 79 | 100.0 | decreased | 8 | 10.0 |
| 0.5 (1-5 cells) | 2 | 2.5 | unchanged | 67 | 83.8 | 0 | 0.0 | unchanged | 71 | 88.8 |
| 1 (6-15 cells) | 0 | 0.0 | increased | 2 | 2.5 | 0 | 0.0 | increased | 0 | 0.0 |
| 2 (16-25 cells) | 0 | 0.0 | total | 80 | 100.0 | 0 | 0.0 | total | 80 | 100.0 |
| 3 (26-50 cells) | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| 4 (>50 cells) | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 79 | 100.0 | | | 79 | 100.0 | | | 158 | 100.0 |

SAS program: P03_T04_02_01.sas - SAS dataset(s): RAND,SLIT

Table 4.2-2 (1 of 1): Slit lamp evaluation during the study - Grade of CELLULARITY of the treated eye during the study and change from Day 1 PP sample

| Visit | GEL (N=78) | | | EYE DROPS (N=80) | | | ALL (N=158) | | | |
|---|-------------------|-------|-------------------|------------------|-------------------|-------|-------------------|-----------|-------------------|-------|
| | Change from Day 1 | | Change from Day 1 | | Change from Day 1 | | Change from Day 1 | | Change from Day 1 | |
| | n | % | n | % | n | % | n | % | n | % |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | |
| 0 grade | 68 | 87.2 | | | 71 | 88.8 | | | 139 | 88.0 |
| 0.5 grade | 6 | 7.7 | | | 4 | 5.0 | | | 10 | 6.3 |
| 1 grade | 4 | 5.1 | | | 5 | 6.3 | | | 9 | 5.7 |
| 2 grade | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| 3 grade | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| 4 grade | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 78 | 100.0 | | | 80 | 100.0 | | | 158 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | |
| 0 (<1 cell) | 73 | 93.6 | decreased | 8 | 10.3 | 78 | 97.5 | decreased | 8 | 10.0 |
| 0.5 (1-5 cells) | 5 | 6.4 | unchanged | 69 | 88.5 | 2 | 2.5 | unchanged | 72 | 90.0 |
| 1 (6-15 cells) | 0 | 0.0 | increased | 1 | 1.3 | 0 | 0.0 | increased | 0 | 0.0 |
| 2 (16-25 cells) | 0 | 0.0 | total | 78 | 100.0 | 0 | 0.0 | total | 80 | 100.0 |
| 3 (26-50 cells) | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| 4 (>50 cells) | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 78 | 100.0 | | | 80 | 100.0 | | | 158 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | |
| 0 (<1 cell) | 78 | 100.0 | decreased | 10 | 12.8 | 79 | 98.8 | decreased | 9 | 11.3 |
| 0.5 (1-5 cells) | 0 | 0.0 | unchanged | 68 | 87.2 | 1 | 1.3 | unchanged | 71 | 88.8 |
| 1 (6-15 cells) | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 |
| 2 (16-25 cells) | 0 | 0.0 | total | 78 | 100.0 | 0 | 0.0 | total | 80 | 100.0 |
| 3 (26-50 cells) | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| 4 (>50 cells) | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 78 | 100.0 | | | 80 | 100.0 | | | 158 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | | | | | |
| 0 (<1 cell) | 75 | 97.4 | decreased | 10 | 12.8 | 79 | 100.0 | decreased | 8 | 10.0 |
| 0.5 (1-5 cells) | 2 | 2.6 | unchanged | 65 | 83.3 | 0 | 0.0 | unchanged | 71 | 88.8 |
| 1 (6-15 cells) | 0 | 0.0 | increased | 2 | 2.6 | 0 | 0.0 | increased | 0 | 0.0 |
| 2 (16-25 cells) | 0 | 0.0 | total | 78 | 100.0 | 0 | 0.0 | total | 80 | 100.0 |
| 3 (26-50 cells) | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| 4 (>50 cells) | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 77 | 100.0 | | | 79 | 100.0 | | | 156 | 100.0 |

SAS program: P03_T04_02_02.sas - SAS dataset(s): RAND,SLIT

**Table 4.3-1 (1 of 1): Slit lamp evaluation during the study - Grade of FLARE of the treated eye during the study and change from Day 1
ITT sample**

| Visit | GEL (N=80) | | EYE DROPS (N=80) | | ALL (N=160) | | |
|---|-------------------|-------|-------------------|----|-------------------|-------|-------|
| | Change from Day 1 | | Change from Day 1 | | Change from Day 1 | | |
| | n | % | n | % | n | % | |
| V3 (day 1 after surgery) - (n %) | | | | | | | |
| None | 58 | 72.5 | | | 53 | 66.3 | |
| Faint | 22 | 27.5 | | | 27 | 33.8 | |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | |
| Marked | 0 | 0.0 | | | 0 | 0.0 | |
| Intense | 0 | 0.0 | | | 0 | 0.0 | |
| Total | 80 | 100.0 | | | 80 | 100.0 | |
| V4 (day 7 after surgery) - (n %) | | | | | | | |
| None | 75 | 93.8 | decreased | 17 | 21.3 | 77 | 96.3 |
| Faint | 5 | 6.3 | unchanged | 63 | 78.8 | 3 | 3.8 |
| Moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 |
| Marked | 0 | 0.0 | total | 80 | 100.0 | 0 | 0.0 |
| Intense | 0 | 0.0 | | | 0 | 0.0 | |
| Total | 80 | 100.0 | | | 80 | 100.0 | |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | |
| None | 80 | 100.0 | decreased | 22 | 27.5 | 80 | 100.0 |
| Faint | 0 | 0.0 | unchanged | 58 | 72.5 | 0 | 0.0 |
| Moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 |
| Marked | 0 | 0.0 | total | 80 | 100.0 | 0 | 0.0 |
| Intense | 0 | 0.0 | | | 0 | 0.0 | |
| Total | 80 | 100.0 | | | 80 | 100.0 | |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | | |
| None | 79 | 100.0 | decreased | 22 | 27.5 | 79 | 100.0 |
| Faint | 0 | 0.0 | unchanged | 57 | 71.3 | 0 | 0.0 |
| Moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 |
| Marked | 0 | 0.0 | total | 80 | 100.0 | 0 | 0.0 |
| Intense | 0 | 0.0 | | | 0 | 0.0 | |
| Total | 79 | 100.0 | | | 79 | 100.0 | |
| | | | | | | | |

SAS program: P03_T04_03_01.sas - SAS dataset(s): RAND,SLIT

**Table 4.3-2 (1 of 1): Slit lamp evaluation during the study - Grade of FLARE of the treated eye during the study and change from Day 1
PP sample**

| Visit | GEL (N=78) | | EYE DROPS (N=80) | | ALL (N=158) | | | | | | | | | | |
|---|-------------------|-------|-------------------|----|-------------------|-------|-------|-----------|-----|-------|-----|-------|-----------|-----|-------|
| | Change from Day 1 | | Change from Day 1 | | Change from Day 1 | | | | | | | | | | |
| | n | % | n | % | n | % | | | | | | | | | |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | | | | | | |
| None | 56 | 71.8 | | | 53 | 66.3 | | | | | | | | | |
| Faint | 22 | 28.2 | | | 27 | 33.8 | | | | | | | | | |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | | | | | | | |
| Marked | 0 | 0.0 | | | 0 | 0.0 | | | | | | | | | |
| Intense | 0 | 0.0 | | | 0 | 0.0 | | | | | | | | | |
| Total | 78 | 100.0 | | | 80 | 100.0 | | | | | | | | | |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | | | | | | |
| None | 73 | 93.6 | decreased | 17 | 21.8 | 77 | 96.3 | decreased | 24 | 30.0 | 150 | 94.9 | decreased | 41 | 25.9 |
| Faint | 5 | 6.4 | unchanged | 61 | 78.2 | 3 | 3.8 | unchanged | 56 | 70.0 | 8 | 5.1 | unchanged | 117 | 74.1 |
| Moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 |
| Marked | 0 | 0.0 | total | 78 | 100.0 | 0 | 0.0 | total | 80 | 100.0 | 0 | 0.0 | total | 158 | 100.0 |
| Intense | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | 0 | 0.0 | | | |
| Total | 78 | 100.0 | | | 80 | 100.0 | | | 158 | 100.0 | | | | | |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | | | | | | |
| None | 78 | 100.0 | decreased | 22 | 28.2 | 80 | 100.0 | decreased | 27 | 33.8 | 158 | 100.0 | decreased | 49 | 31.0 |
| Faint | 0 | 0.0 | unchanged | 56 | 71.8 | 0 | 0.0 | unchanged | 53 | 66.3 | 0 | 0.0 | unchanged | 109 | 69.0 |
| Moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 |
| Marked | 0 | 0.0 | total | 78 | 100.0 | 0 | 0.0 | total | 80 | 100.0 | 0 | 0.0 | total | 158 | 100.0 |
| Intense | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | 0 | 0.0 | | | |
| Total | 78 | 100.0 | | | 80 | 100.0 | | | 158 | 100.0 | | | | | |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | | | | | | | | | | |
| None | 77 | 100.0 | decreased | 22 | 28.2 | 79 | 100.0 | decreased | 26 | 32.5 | 156 | 100.0 | decreased | 48 | 30.4 |
| Faint | 0 | 0.0 | unchanged | 55 | 70.5 | 0 | 0.0 | unchanged | 53 | 66.3 | 0 | 0.0 | unchanged | 108 | 68.4 |
| Moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 |
| Marked | 0 | 0.0 | total | 78 | 100.0 | 0 | 0.0 | total | 80 | 100.0 | 0 | 0.0 | total | 158 | 100.0 |
| Intense | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | 0 | 0.0 | | | |
| Total | 77 | 100.0 | | | 79 | 100.0 | | | 156 | 100.0 | | | | | |

SAS program: P03_T04_03_02.sas - SAS dataset(s): RAND,SLIT

Table 4.4-1 (1 of 2): Slit lamp evaluation during the study - Summary of study drug response at endpoint stratified by sex, age and centre ITT sample

| Variable | GEL (N=80) | | EYE DROPS (N=80) | | ALL (N=160) | |
|-----------------------------|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Whole sample - (n %) | | | | | | |
| full responder | 72 | 90.0 | 76 | 95.0 | 148 | 92.5 |
| partial responder | 8 | 10.0 | 4 | 5.0 | 12 | 7.5 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| Sex - (n %) | | | | | | |
| Male | | | | | | |
| full responder | 35 | 94.6 | 23 | 95.8 | 58 | 95.1 |
| partial responder | 2 | 5.4 | 1 | 4.2 | 3 | 4.9 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 37 | 100.0 | 24 | 100.0 | 61 | 100.0 |
| Female | | | | | | |
| full responder | 37 | 86.0 | 53 | 94.6 | 90 | 90.9 |
| partial responder | 6 | 14.0 | 3 | 5.4 | 9 | 9.1 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 43 | 100.0 | 56 | 100.0 | 99 | 100.0 |
| Age | | | | | | |
| <=65 yrs | | | | | | |
| full responder | 15 | 93.8 | 11 | 84.6 | 26 | 89.7 |
| partial responder | 1 | 6.3 | 2 | 15.4 | 3 | 10.3 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 16 | 100.0 | 13 | 100.0 | 29 | 100.0 |
| 66-74 yrs | | | | | | |
| full responder | 32 | 88.9 | 28 | 100.0 | 60 | 93.8 |
| partial responder | 4 | 11.1 | 0 | 0.0 | 4 | 6.3 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 36 | 100.0 | 28 | 100.0 | 64 | 100.0 |
| >=75 yrs | | | | | | |
| full responder | 25 | 89.3 | 37 | 94.9 | 62 | 92.5 |
| partial responder | 3 | 10.7 | 2 | 5.1 | 5 | 7.5 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 28 | 100.0 | 39 | 100.0 | 67 | 100.0 |

Table 4.4-1 (2 of 2): Slit lamp evaluation during the study - Summary of study drug response at endpoint stratified by sex, age and centre ITT sample

| Variable | GEL (N=80) | | EYE DROPS (N=80) | | ALL (N=160) | |
|-------------------|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Centre | | | | | | |
| 1001 (Rome) | | | | | | |
| full responder | 27 | 96.4 | 26 | 100.0 | 53 | 98.1 |
| partial responder | 1 | 3.6 | 0 | 0.0 | 1 | 1.9 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 28 | 100.0 | 26 | 100.0 | 54 | 100.0 |
| 1002 (Florence) | | | | | | |
| full responder | 15 | 75.0 | 19 | 86.4 | 34 | 81.0 |
| partial responder | 5 | 25.0 | 3 | 13.6 | 8 | 19.0 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 20 | 100.0 | 22 | 100.0 | 42 | 100.0 |
| 1003 (Milan) | | | | | | |
| full responder | 25 | 100.0 | 25 | 100.0 | 50 | 100.0 |
| partial responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 25 | 100.0 | 25 | 100.0 | 50 | 100.0 |
| Germany | | | | | | |
| full responder | 5 | 71.4 | 6 | 85.7 | 11 | 78.6 |
| partial responder | 2 | 28.6 | 1 | 14.3 | 3 | 21.4 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 7 | 100.0 | 7 | 100.0 | 14 | 100.0 |

SAS program: P03_T04_04_01.sas - SAS dataset(s): RAND,SLIT

NOTE:

Responder is the patient who shows a decrease of the degree at endpoint respect to baseline or absence of degree in both the visits.

Based on this definition, the patients in analysis were classified as follows:

Full responder = both cellularity and flare measurements with degree zero at endpoint or absence of degree both at baseline and endpoint

Partial responder = only one response for the two measurements

No responder = no response for both measurements

Table 4.4-2 (1 of 2): Slit lamp evaluation during the study - Summary of study drug response at endpoint stratified by sex, age and centre PP sample

| Variable | GEL (N=78) | | EYE DROPS (N=80) | | ALL (N=158) | |
|-----------------------------|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Whole sample - (n %) | | | | | | |
| full responder | 70 | 89.7 | 76 | 95.0 | 146 | 92.4 |
| partial responder | 8 | 10.3 | 4 | 5.0 | 12 | 7.6 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 78 | 100.0 | 80 | 100.0 | 158 | 100.0 |
| Sex - (n %) | | | | | | |
| Male | | | | | | |
| full responder | 34 | 94.4 | 23 | 95.8 | 57 | 95.0 |
| partial responder | 2 | 5.6 | 1 | 4.2 | 3 | 5.0 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 36 | 100.0 | 24 | 100.0 | 60 | 100.0 |
| Female | | | | | | |
| full responder | 36 | 85.7 | 53 | 94.6 | 89 | 90.8 |
| partial responder | 6 | 14.3 | 3 | 5.4 | 9 | 9.2 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 42 | 100.0 | 56 | 100.0 | 98 | 100.0 |
| Age | | | | | | |
| <=65 yrs | | | | | | |
| full responder | 13 | 92.9 | 11 | 84.6 | 24 | 88.9 |
| partial responder | 1 | 7.1 | 2 | 15.4 | 3 | 11.1 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 14 | 100.0 | 13 | 100.0 | 27 | 100.0 |
| 66-74 yrs | | | | | | |
| full responder | 32 | 88.9 | 28 | 100.0 | 60 | 93.8 |
| partial responder | 4 | 11.1 | 0 | 0.0 | 4 | 6.3 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 36 | 100.0 | 28 | 100.0 | 64 | 100.0 |
| >=75 yrs | | | | | | |
| full responder | 25 | 89.3 | 37 | 94.9 | 62 | 92.5 |
| partial responder | 3 | 10.7 | 2 | 5.1 | 5 | 7.5 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 28 | 100.0 | 39 | 100.0 | 67 | 100.0 |

Table 4.4-2 (2 of 2): Slit lamp evaluation during the study - Summary of study drug response at endpoint stratified by sex, age and centre PP sample

| Variable | GEL (N=78) | | EYE DROPS (N=80) | | ALL (N=158) | |
|-------------------|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Centre | | | | | | |
| 1001 (Rome) | | | | | | |
| full responder | 27 | 96.4 | 26 | 100.0 | 53 | 98.1 |
| partial responder | 1 | 3.6 | 0 | 0.0 | 1 | 1.9 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 28 | 100.0 | 26 | 100.0 | 54 | 100.0 |
| 1002 (Florence) | | | | | | |
| full responder | 15 | 75.0 | 19 | 86.4 | 34 | 81.0 |
| partial responder | 5 | 25.0 | 3 | 13.6 | 8 | 19.0 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 20 | 100.0 | 22 | 100.0 | 42 | 100.0 |
| 1003 (Milan) | | | | | | |
| full responder | 23 | 100.0 | 25 | 100.0 | 48 | 100.0 |
| partial responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 23 | 100.0 | 25 | 100.0 | 48 | 100.0 |
| Germany | | | | | | |
| full responder | 5 | 71.4 | 6 | 85.7 | 11 | 78.6 |
| partial responder | 2 | 28.6 | 1 | 14.3 | 3 | 21.4 |
| no responder | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 7 | 100.0 | 7 | 100.0 | 14 | 100.0 |

SAS program: P03_T04_04_02.sas - SAS dataset(s): RAND,SLIT

NOTE:

Responder is the patient who shows a decrease of the degree at endpoint respect to baseline or absence of degree in both the visits.

Based on this definition, the patients in analysis were classified as follows:

Full responder = both cellularity and flare measurements with degree zero at endpoint or absence of degree both at baseline and endpoint

Partial responder = only one response for the two measurements

No responder = no response for both measurements

Table 4.5-1 (1 of 1): Slit lamp evaluation during the study
Analysis to test the noninferiority of GEL group (test) vs. EYE DROPS group (control) on occurrence of full-responder at endpoint
ITT sample

| Study drug | Observed results | | Non inferiority margin | Test | Estimated risk difference | 97.5% Confidence interval | |
|------------|------------------|------|------------------------|--------------------|---------------------------|---------------------------|--------|
| | n/N | % | | | | Lower | Upper |
| GEL | 72/80 | 90.0 | -0.10 | Univariate test | -0.0500 | -0.0580 | 0.1580 |
| EYE DROPS | 76/80 | 95.0 | | Multivariate test* | -0.0576 | -0.0378 | 0.1530 |

SAS program: P03_T04_05_01.sas - SAS dataset(s): RAND,SLIT

* The co-factors Sex and Age were considered in the model
The co-factor Site were not considered due the very small number of patients (N=14) for Germany

Table 4.5-2 (1 of 1): Slit lamp evaluation during the study
Analysis to test the noninferiority of GEL group (test) vs. EYE DROPS group (control) on occurrence of full-responder at endpoint
PP sample

| Study drug | Observed results | | Non inferiority margin | Test | Estimated risk difference | 97.5% Confidence interval | |
|------------|------------------|------|------------------------|--------------------|---------------------------|---------------------------|--------|
| | n/N | % | | | | Lower | Upper |
| GEL | 70/78 | 89.7 | -0.10 | Univariate test | -0.0526 | -0.0562 | 0.1613 |
| EYE DROPS | 76/80 | 95.0 | | Multivariate test* | -0.0599 | -0.0366 | 0.1564 |

SAS program: P03_T04_05_02.sas - SAS dataset(s): RAND,SLIT

* The co-factors Sex and Age were considered in the model
The co-factor Site were not considered due the very small number of patients (N=14) for Germany

Table 4.6-1 (1 of 1): Slit lamp evaluation during the study
Analysis to test the noninferiority of GEL group (test) vs. DRP group (control) on occurrence of full-responder at Visit 5 (Day 15)
ITT sample

| Study drug | Observed results | | Non inferiority margin | Test | Estimated risk difference | 97.5% Confidence interval | |
|---------------|------------------|-------|------------------------|---------------------------------------|--------------------------------|---------------------------|-------|
| | n/N | % | | | | Lower | Upper |
| GEL EYE DROPS | 80/80 | 100.0 | -0.10 | Univariate test Multivariate test* | not evaluable not evaluable | | |
| | 80/80 | 100.0 | | | | | |

SAS program: P03_T04_06_01.sas - SAS dataset(s): RAND,SLIT

* The co-factors Sex and Age were considered in the model
The co-factor Site were not considered due the very small number of patients (N=14) for Germany

Table 4.6-2 (1 of 1): Slit lamp evaluation during the study
Analysis to test the noninferiority of GEL group (test) vs. DRP group (control) on occurrence of full-responder at Visit 5 (Day 15)
PP sample

| Study drug | Observed results | | Non inferiority margin | Test | Estimated risk difference | 97.5% Confidence interval | |
|---------------|------------------|-------|------------------------|---------------------------------------|--------------------------------|---------------------------|-------|
| | n/N | % | | | | Lower | Upper |
| GEL EYE DROPS | 78/78 | 100.0 | -0.10 | Univariate test Multivariate test* | not evaluable not evaluable | | |
| | 80/80 | 100.0 | | | | | |

SAS program: P03_T04_06_02.sas - SAS dataset(s): RAND,SLIT

* The co-factors Sex and Age were considered in the model
The co-factor Site were not considered due the very small number of patients (N=14) for Germany

Table 4.7-1 (1 of 1): Slit lamp evaluation during the study
Grade of FLARE of the treated eye during the study only for patients showing degree greater than zero at Visit 3 (Day 7)
ITT sample

| Visit | GEL (N=22/80) | | EYE DROPS (N=27/80) | | ALL (N=49/160) | |
|---|------------------|-------|------------------------|-------|-------------------|-------|
| | n | % | n | % | n | % |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| None | 17 | 77.3 | 24 | 88.9 | 41 | 83.7 |
| Faint | 5 | 22.7 | 3 | 11.1 | 8 | 16.3 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Marked | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Intense | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 22 | 100.0 | 27 | 100.0 | 49 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| None | 22 | 100.0 | 27 | 100.0 | 49 | 100.0 |
| Faint | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Marked | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Intense | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 22 | 100.0 | 27 | 100.0 | 49 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | |
| None | 22 | 100.0 | 26 | 100.0 | 48 | 100.0 |
| Faint | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Marked | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Intense | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 22 | 100.0 | 26 | 100.0 | 48 | 100.0 |

SAS program: P03_T04_07_01.sas - SAS dataset(s): RAND,SLIT

Table 4.7-2 (1 of 1): Slit lamp evaluation during the study
Grade of FLARE of the treated eye during the study only for patients showing degree greater than zero at Visit 3 (Day 7)
PP sample

| Visit | GEL (N=22/78) | | EYE DROPS (N=27/80) | | ALL (N=49/158) | |
|---|------------------|-------|------------------------|-------|-------------------|-------|
| | n | % | n | % | n | % |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| None | 17 | 77.3 | 24 | 88.9 | 41 | 83.7 |
| Faint | 5 | 22.7 | 3 | 11.1 | 8 | 16.3 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Marked | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Intense | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 22 | 100.0 | 27 | 100.0 | 49 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| None | 22 | 100.0 | 27 | 100.0 | 49 | 100.0 |
| Faint | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Marked | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Intense | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 22 | 100.0 | 27 | 100.0 | 49 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | |
| None | 22 | 100.0 | 26 | 100.0 | 48 | 100.0 |
| Faint | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Moderate | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Marked | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Intense | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 22 | 100.0 | 26 | 100.0 | 48 | 100.0 |

SAS program: P03_T04_07_02.sas - SAS dataset(s): RAND,SLIT

Table 4.8-1 (1 of 1): Slit lamp evaluation during the study
Grade of CELLULARITY of the treated eye during the study only for patients showing degree greater than zero at Visit 3 (Day 7)
ITT sample

| Visit | GEL (N=10/80) | | EYE DROPS (N=9/80) | | ALL (N=19/160) | |
|---|------------------|-------|-----------------------|-------|-------------------|-------|
| | n | % | n | % | n | % |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| 0 grade | 6 | 60.0 | 7 | 77.8 | 13 | 68.4 |
| 0.5 grade | 4 | 40.0 | 2 | 22.2 | 6 | 31.6 |
| 1 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 2 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 3 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 4 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 10 | 100.0 | 9 | 100.0 | 19 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| 0 grade | 10 | 100.0 | 8 | 88.9 | 18 | 94.7 |
| 0.5 grade | 0 | 0.0 | 1 | 11.1 | 1 | 5.3 |
| 1 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 2 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 3 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 4 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 10 | 100.0 | 9 | 100.0 | 19 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | |
| 0 grade | 10 | 100.0 | 8 | 100.0 | 18 | 100.0 |
| 0.5 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 1 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 2 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 3 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 4 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 10 | 100.0 | 8 | 100.0 | 18 | 100.0 |

SAS program: P03_T04_08_01.sas - SAS dataset(s): RAND,SLIT

Table 4.8-2 (1 of 1): Slit lamp evaluation during the study
Grade of CELLULARITY of the treated eye during the study only for patients showing degree greater than zero at Visit 3 (Day 7)
PP sample

| Visit | GEL (N=10/78) | | EYE DROPS (N=9/80) | | ALL (N=19/158) | |
|---|------------------|-------|-----------------------|-------|-------------------|-------|
| | n | % | n | % | n | % |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| 0 grade | 6 | 60.0 | 7 | 77.8 | 13 | 68.4 |
| 0.5 grade | 4 | 40.0 | 2 | 22.2 | 6 | 31.6 |
| 1 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 2 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 3 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 4 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 10 | 100.0 | 9 | 100.0 | 19 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| 0 grade | 10 | 100.0 | 8 | 88.9 | 18 | 94.7 |
| 0.5 grade | 0 | 0.0 | 1 | 11.1 | 1 | 5.3 |
| 1 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 2 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 3 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 4 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 10 | 100.0 | 9 | 100.0 | 19 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | |
| 0 grade | 10 | 100.0 | 8 | 100.0 | 18 | 100.0 |
| 0.5 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 1 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 2 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 3 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 4 grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 10 | 100.0 | 8 | 100.0 | 18 | 100.0 |

SAS program: P03_T04_08_02.sas - SAS dataset(s): RAND,SLIT

**Table 4.9 (1 of 1): Microbial load during the study - - Frequency of test execution
ITT sample**

| Visit | GEL (N=80) | | EYE DROPS (N=80) | | ALL (N=160) | |
|----------------------------------|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| No | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| Yes | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| No | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |
| Yes | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 80 | 100.0 | 80 | 100.0 | 160 | 100.0 |

SAS program: P03_T04_09.sas - SAS dataset(s): RAND,MICRO-LOAD

5. Medications

**Table 5.1 (1 of 6): Number of patients with concomitant medications, by ATC therapeutic class and preferred term
Safety sample**

| ATC Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| Subjects with at least one concomitant medication | 61 | 71.8 | 55 | 66.3 | 116 | 69.0 |
| ----- | ----- | ----- | ----- | ----- | ----- | ----- |
| ALIMENTARY TRACT AND METABOLISM | 14 | 16.5 | 8 | 9.6 | 22 | 13.1 |
| ALKALA N | 1 | 1.2 | . | . | 1 | 0.6 |
| CALCIUM | 1 | 1.2 | . | . | 1 | 0.6 |
| CALCIUM GLUCONATE | 1 | 1.2 | . | . | 1 | 0.6 |
| COLECALCIFEROL | 4 | 4.7 | 1 | 1.2 | 5 | 3.0 |
| ESOMEPRAZOLE | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 |
| INSULIN HUMAN | . | . | 1 | 1.2 | 1 | 0.6 |
| LACTULOSE | . | . | 1 | 1.2 | 1 | 0.6 |
| LANSOPRAZOLE | . | . | 2 | 2.4 | 2 | 1.2 |
| LEKOVIT CA | 1 | 1.2 | . | . | 1 | 0.6 |
| LEVOCARNITINE | 1 | 1.2 | . | . | 1 | 0.6 |
| METFORMIN | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| METOCLOPRAMIDE | 1 | 1.2 | . | . | 1 | 0.6 |
| MOVICOL | 1 | 1.2 | . | . | 1 | 0.6 |
| OMEPRAZOLE | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| PANTOPRAZOLE | 3 | 3.5 | 1 | 1.2 | 4 | 2.4 |
| SITAGLIPTIN | . | . | 1 | 1.2 | 1 | 0.6 |
| THIOCTIC ACID | 1 | 1.2 | . | . | 1 | 0.6 |
| UBIDECARENONE | 1 | 1.2 | . | . | 1 | 0.6 |
| URSODEOXYCHOLIC ACID | 1 | 1.2 | . | . | 1 | 0.6 |
| ANTIINFECTIVES FOR SYSTEMIC USE | 7 | 8.2 | 6 | 7.2 | 13 | 7.7 |
| CEFUROXIME | 7 | 8.2 | 6 | 7.2 | 13 | 7.7 |
| ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| IMATINIB | . | . | 1 | 1.2 | 1 | 0.6 |
| MYCOPHENOLIC ACID | 1 | 1.2 | . | . | 1 | 0.6 |
| ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENT | . | . | 1 | 1.2 | 1 | 0.6 |
| HYDROXYCHLOROQUINE | . | . | 1 | 1.2 | 1 | 0.6 |

**Table 5.1 (2 of 6): Number of patients with concomitant medications, by ATC therapeutic class and preferred term
Safety sample**

| ATC Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--------------------------------|---------------|------|---------------------|------|----------------|------|
| | n | % | n | % | n | % |
| BLOOD AND BLOOD FORMING ORGANS | | | | | | |
| ACETYLSALICYLIC ACID | 16 | 18.8 | 17 | 20.5 | 33 | 19.6 |
| CLOPIDOGREL | 12 | 14.1 | 12 | 14.5 | 24 | 14.3 |
| DABIGATRAN | 1 | 1.2 | 3 | 3.6 | 4 | 2.4 |
| EDOXABAN | 2 | 2.4 | . | . | 2 | 1.2 |
| FONDAPARINUX | . | . | 2 | 2.4 | 2 | 1.2 |
| HYDROXOCOBALAMIN | 1 | 1.2 | . | . | 1 | 0.6 |
| MESOGLYCAN | . | . | 1 | 1.2 | 1 | 0.6 |
| WARFARIN | . | . | 1 | 1.2 | 1 | 0.6 |

**Table 5.1 (3 of 6): Number of patients with concomitant medications, by ATC therapeutic class and preferred term
Safety sample**

| ATC Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|-----------------------------------|---------------|------|---------------------|------|----------------|------|
| | n | % | n | % | n | % |
| CARDIOVASCULAR SYSTEM | | | | | | |
| AMIODARONE | 49 | 57.6 | 46 | 55.4 | 95 | 56.5 |
| AMLODIPINE | 1 | 1.2 | . | . | 1 | 0.6 |
| ATENOLOL | 4 | 4.7 | 2 | 2.4 | 6 | 3.6 |
| ATORVASTATIN | 2 | 2.4 | 3 | 3.6 | 5 | 3.0 |
| BENICAR HCT | 6 | 7.1 | 5 | 6.0 | 11 | 6.5 |
| BISOPROLOL | . | . | 1 | 1.2 | 1 | 0.6 |
| BOSENTAN | 6 | 7.1 | 8 | 9.6 | 14 | 8.3 |
| CANDESARTAN | 1 | 1.2 | . | . | 1 | 0.6 |
| CANDESARTAN W/HYDROCHLOROTHIAZIDE | 4 | 4.7 | 2 | 2.4 | 6 | 3.6 |
| CANRENOIC ACID | . | . | 1 | 1.2 | 1 | 0.6 |
| CARACE PLUS | . | . | 1 | 1.2 | 1 | 0.6 |
| CARVEDILOL | 2 | 2.4 | . | . | 2 | 1.2 |
| CHLORTALIDONE | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| CO-DIOVAN | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 |
| DELAPRIDE | 1 | 1.2 | . | . | 1 | 0.6 |
| DILTIAZEM | . | . | 1 | 1.2 | 1 | 0.6 |
| ENALAPRIL | . | . | 2 | 2.4 | 2 | 1.2 |
| FENOFIBRATE | 1 | 1.2 | . | . | 1 | 0.6 |
| FISH OIL | . | . | 1 | 1.2 | 1 | 0.6 |
| FOSINOPRIL | . | . | 1 | 1.2 | 1 | 0.6 |
| FUROSEMIDE | . | . | 3 | 3.6 | 3 | 1.8 |
| GLYCERYL TRINITRATE | . | . | 1 | 1.2 | 1 | 0.6 |
| HYDROCHLOROTHIAZIDE | . | . | 1 | 1.2 | 1 | 0.6 |
| IRBESARTAN | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| ISOSORBIDE | . | . | 1 | 1.2 | 1 | 0.6 |
| KARVEA HCT | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| LACIDIPINE | 1 | 1.2 | . | . | 1 | 0.6 |
| LERCANIDIPINE | . | . | 2 | 2.4 | 2 | 1.2 |
| LISINOPRIL | 5 | 5.9 | . | . | 5 | 3.0 |
| LOSARTAN | 2 | 2.4 | . | . | 2 | 1.2 |
| METHYLDOPA | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| METOPROLOL | 3 | 3.5 | 3 | 3.6 | 6 | 3.6 |
| MODURETIC | 2 | 2.4 | 2 | 2.4 | 4 | 2.4 |
| NEBICARD-H | . | . | 2 | 2.4 | 2 | 1.2 |
| NEBIVOLOL | 3 | 3.5 | 5 | 6.0 | 8 | 4.8 |
| NIFEDIPIINE | 1 | 1.2 | . | . | 1 | 0.6 |
| OLMESAFE AM | 1 | 1.2 | . | . | 1 | 0.6 |
| (cont'd) | | | | | | |

**Table 5.1 (4 of 6): Number of patients with concomitant medications, by ATC therapeutic class and preferred term
Safety sample**

| ATC Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|------|---------------------|-----|----------------|-----|
| | n | % | n | % | n | % |
| CARDIOVASCULAR SYSTEM | | | | | | |
| OLMESARTAN | . | . | 1 | 1.2 | 1 | 0.6 |
| RAMIPRIL | 9 | 10.6 | 5 | 6.0 | 14 | 8.3 |
| ROSUVASTATIN | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| SILDENAFIL | 1 | 1.2 | . | . | 1 | 0.6 |
| SIMVASTATIN | 7 | 8.2 | 6 | 7.2 | 13 | 7.7 |
| SOTALOL | 2 | 2.4 | . | . | 2 | 1.2 |
| TELMISARTAN | . | . | 1 | 1.2 | 1 | 0.6 |
| VALSARTAN | 1 | 1.2 | 3 | 3.6 | 4 | 2.4 |
| VERAPAMIL | 1 | 1.2 | . | . | 1 | 0.6 |
| GENITO URINARY SYSTEM AND SEX HORMONES | | | | | | |
| ALFUZOSIN | 2 | 2.4 | 3 | 3.6 | 5 | 3.0 |
| DUTASTERIDE | 1 | 1.2 | . | . | 1 | 0.6 |
| FINASTERIDE | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| TAMSULOSIN | . | . | 1 | 1.2 | 1 | 0.6 |
| MUSCULO-SKELETAL SYSTEM | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 |
| ALENDRONIC ACID | 7 | 8.2 | 3 | 3.6 | 10 | 6.0 |
| ALLOPURINOL | 2 | 2.4 | . | . | 2 | 1.2 |
| FOSAVANCE | 3 | 3.5 | 2 | 2.4 | 5 | 3.0 |
| IBANDRONIC ACID | . | . | 1 | 1.2 | 1 | 0.6 |
| RISEDRONIC ACID | 1 | 1.2 | . | . | 1 | 0.6 |

**Table 5.1 (5 of 6): Number of patients with concomitant medications, by ATC therapeutic class and preferred term
Safety sample**

| ATC Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|-----------------------------|---------------|------|---------------------|-----|----------------|------|
| | n | % | n | % | n | % |
| NERVOUS SYSTEM | | | | | | |
| ADEMETIONINE | 16 | 18.8 | 8 | 9.6 | 24 | 14.3 |
| ALPRAZOLAM | 1 | 1.2 | . | . | 1 | 0.6 |
| BETAHISTINE | 2 | 2.4 | . | . | 2 | 1.2 |
| BROMAZEPAM | 1 | 1.2 | . | . | 1 | 0.6 |
| BROTIZOLAM | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| CITALOPRAM | . | . | 1 | 1.2 | 1 | 0.6 |
| ESCITALOPRAM | 1 | 1.2 | . | . | 1 | 0.6 |
| FENTANYL | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| LORAZEPAM | . | . | 1 | 1.2 | 1 | 0.6 |
| METAMIZOLE | 2 | 2.4 | 1 | 1.2 | 3 | 1.8 |
| NITRAZEPAM | 1 | 1.2 | . | . | 1 | 0.6 |
| OLANZAPINE | 7 | 8.2 | 5 | 6.0 | 12 | 7.1 |
| PAROXETINE | . | . | 1 | 1.2 | 1 | 0.6 |
| PRILOCAINE | 1 | 1.2 | . | . | 1 | 0.6 |
| VALPROIC ACID | 7 | 8.2 | 4 | 4.8 | 11 | 6.5 |
| | 1 | 1.2 | . | . | 1 | 0.6 |
| RESPIRATORY SYSTEM | . | . | 2 | 2.4 | 2 | 1.2 |
| CETIRIZINE | . | . | 1 | 1.2 | 1 | 0.6 |
| DUOVENT | . | . | 1 | 1.2 | 1 | 0.6 |
| TIOTROPIUM | . | . | 1 | 1.2 | 1 | 0.6 |
| SENSORY ORGANS | | | | | | |
| BRIMONIDINE | 8 | 9.4 | 8 | 9.6 | 16 | 9.5 |
| BRINZOLAMIDE | 1 | 1.2 | . | . | 1 | 0.6 |
| COSOPT | . | . | 1 | 1.2 | 1 | 0.6 |
| DEXPANTHENOL | 2 | 2.4 | . | . | 2 | 1.2 |
| DICLOFENAC | 1 | 1.2 | . | . | 1 | 0.6 |
| EPINEPHRINE | . | . | 1 | 1.2 | 1 | 0.6 |
| HYALURONIC ACID | 5 | 5.9 | . | . | 5 | 3.0 |
| HYLO PARIN | . | . | 2 | 2.4 | 2 | 1.2 |
| HYPROMELLOSE | . | . | 1 | 1.2 | 1 | 0.6 |
| NEPAFENAC | . | . | 1 | 1.2 | 1 | 0.6 |
| OFLOXACIN | . | . | 1 | 1.2 | 1 | 0.6 |
| PHENYLEPHRINE W/TROPICAMIDE | 4 | 4.7 | 4 | 4.8 | 8 | 4.8 |
| PREDNISOLONE | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| SYSTANE LUBRICANT | . | . | 1 | 1.2 | 1 | 0.6 |
| TIMOLOL | 1 | 1.2 | . | . | 1 | 0.6 |
| TROPICAMIDE | 2 | 2.4 | 1 | 1.2 | 3 | 1.8 |

**Table 5.1 (6 of 6): Number of patients with concomitant medications, by ATC therapeutic class and preferred term
Safety sample**

| ATC Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--|---------------|-----|---------------------|------|----------------|-----|
| | n | % | n | % | n | % |
| SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES | 6 | 7.1 | 10 | 12.0 | 16 | 9.5 |
| LEVOTHYROXINE | 6 | 7.1 | 8 | 9.6 | 14 | 8.3 |
| PREDNISOLONE | . | . | 1 | 1.2 | 1 | 0.6 |
| TERIPARATIDE | . | . | 1 | 1.2 | 1 | 0.6 |
| VARIOUS | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| CUCURBITA PEPO | 1 | 1.2 | . | . | 1 | 0.6 |
| GENERAL NUTRIENTS | 1 | 1.2 | . | . | 1 | 0.6 |
| SERENOA REPENS | . | . | 1 | 1.2 | 1 | 0.6 |

SAS program: P02_T05_01.sas - SAS dataset(s):

Note:

- A subject with multiple occurrences is counted only once in the respective category.
- Arranged alphabetically

**Table 5.2 (1 of 1): Number of patients assuming study drugs during the study
Safety sample**

| Visit | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|-------|---------------------|-------|-----------------|-------|
| | n | % | n | % | n | % |
| V2 (surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 3 | 3.6 | 3 | 1.8 |
| Yes | 83 | 100.0 | 80 | 96.4 | 163 | 98.2 |
| Total | 83 | 100.0 | 83 | 100.0 | 166 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| No | 3 | 3.6 | 0 | 0.0 | 3 | 1.8 |
| Yes | 80 | 96.4 | 82 | 100.0 | 162 | 98.2 |
| Total | 83 | 100.0 | 82 | 100.0 | 165 | 100.0 |

SAS program: P03_T05_02.sas - SAS dataset(s): RAND,TREATMENT

6. Safety evaluation

6.1 Intra Ocular Pressure

**Table 6.1-1 (1 of 1): Intra ocular pressure on treated eye - Point estimate of IOP and change from Visit 1
Safety sample**

| Visit | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|------------|------|---------------------|------|---------------------|------|
| | | | Change from Visit 1 | | Change from Visit 1 | |
| V1 (before surgery) - (n %) | | | | | | |
| N | 85 | | 83 | | 168 | |
| Mean | 15.3 | | 15.4 | | 15.4 | |
| SD | 1.9 | | 1.8 | | 1.9 | |
| Median | 16.0 | | 16.0 | | 16.0 | |
| Range | 10.0 | 19.0 | 10.0 | 20.0 | 10.0 | 20.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| N | 83 | 83 | 83 | 83 | 166 | 166 |
| Mean | 16.0 | 0.7 | 15.6 | 0.2 | 15.8 | 0.4 |
| SD | 2.7 | 2.5 | 2.2 | 2.2 | 2.4 | 2.4 |
| Median | 16.0 | 0.0 | 16.0 | 0.0 | 16.0 | 0.0 |
| Range | 12.0 | 34.0 | -4.0 | 15.0 | 11.0 | 34.0 |
| 95 CI | | 0.1 | 1.2 | | -0.2 | 0.7 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| N | 83 | 83 | 82 | 82 | 165 | 165 |
| Mean | 15.0 | -0.3 | 14.8 | -0.6 | 14.9 | -0.5 |
| SD | 2.0 | 1.9 | 1.7 | 2.1 | 1.8 | 2.0 |
| Median | 16.0 | 0.0 | 15.0 | 0.0 | 15.0 | 0.0 |
| Range | 9.0 | 19.0 | -7.0 | 4.0 | 10.0 | 19.0 |
| 95 CI | | -0.8 | 0.1 | | -1.0 | -0.1 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| N | 81 | 81 | 81 | 81 | 162 | 162 |
| Mean | 14.8 | -0.6 | 14.9 | -0.5 | 14.8 | -0.5 |
| SD | 2.0 | 2.1 | 1.9 | 2.2 | 2.0 | 2.2 |
| Median | 15.0 | 0.0 | 15.0 | 0.0 | 15.0 | 0.0 |
| Range | 8.0 | 18.0 | -8.0 | 6.0 | 10.0 | 21.0 |
| 95 CI | | -1.0 | -0.1 | | -1.0 | 0.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | |
| N | 80 | 80 | 80 | 80 | 160 | 160 |
| Mean | 14.4 | -0.9 | 14.6 | -0.7 | 14.5 | -0.8 |
| SD | 1.7 | 1.9 | 1.7 | 2.1 | 1.7 | 2.0 |
| Median | 15.0 | -1.0 | 15.0 | -1.0 | 15.0 | -1.0 |
| Range | 9.0 | 18.0 | -6.0 | 5.0 | 10.0 | 20.0 |
| 95 CI | | -1.3 | -0.4 | | -1.1 | -0.2 |

SAS program: P03_T06_01_01.sas - SAS dataset(s): RAND, SURGERY, INTRA_PRES

Listing of patients with an increment of IOP between visits greater or equal to 6 mmHg during the study - Safety sample

| Subj. code | Study drug | Sex | Age | Change from Screening | | | | Change between visits | | |
|---------------|---------------|--------|-----|------------------------|------------------------|-------------------------|-------------------------|-----------------------|-----------------------|------------------------|
| | | | | Day 1 vs Screen. | Day 7 vs Screen. | Day 15 vs Screen. | Day 60 vs Screen. | Day 1 vs Day 7 | Day 7 vs Day 15 | Day 15 vs Day 60 |
| | | | | | | | | | | |
| 100327 | GEL | Female | 74 | 7 | -3 | -2 | -3 | -10 | 1 | -1 |
| 100345 | GEL | Male | 48 | 6 | 4 | 6 | 5 | -2 | 2 | -1 |
| 100347 | GEL | Male | 57 | 6 | 4 | 3 | 4 | -2 | -1 | 1 |
| 200101 | GEL | Female | 65 | 15 | -3 | -2 | -3 | -18 | 1 | -1 |
| 100101 | EYE DROPS | Female | 84 | -1 | 5 | 4 | 3 | 6 | -1 | -1 |
| 100312 | EYE DROPS | Female | 71 | -1 | -1 | 6 | 5 | 0 | 7 | -1 |
| 100316 | EYE DROPS | Male | 76 | 0 | -4 | 2 | -1 | -4 | 6 | -3 |
| 100326 | EYE DROPS | Male | 81 | 2 | -5 | -5 | 1 | -7 | 0 | 6 |
| 100328 | EYE DROPS | Male | 83 | 6 | -1 | -2 | 0 | -7 | -1 | 2 |
| 100344 | EYE DROPS | Female | 68 | 8 | 6 | 5 | 6 | -2 | -1 | 1 |
| 200112 | EYE DROPS | Male | 85 | 6 | -2 | 2 | -4 | -8 | 4 | -6 |
| 200202 | EYE DROPS | Female | 71 | 6 | 3 | 2 | 0 | -3 | -1 | -2 |

Listing produced from SAS program P03_T06_01_02 IOP change.sas - SAS dataset(s): RAND, INTRA_PRES

**Table 6.1-2 (1 of 1): Intra ocular pressure on non-treated eye - Point estimate of IOP and change from Visit 1
Safety sample**

| Visit | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--|------------|------|---------------------|------|---------------------|-----------|
| | | | Change from Visit 1 | | Change from Visit 1 | |
| V1 (before surgery) - (n %) | | | | | | |
| N | | 85 | | 83 | | 168 |
| Mean | | 15.1 | | 15.2 | | 15.1 |
| SD | | 2.0 | | 1.7 | | 1.8 |
| Median | | 15.0 | | 15.0 | | 15.0 |
| Range | 10.0 | 20.0 | | 10.0 | 19.0 | 10.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| N | | 83 | 83 | 83 | 83 | 166 |
| Mean | | 15.6 | 0.4 | 15.3 | 0.2 | 15.5 |
| SD | | 2.0 | 2.2 | 1.8 | 2.0 | 1.9 |
| Median | | 16.0 | 0.0 | 15.0 | 0.0 | 16.0 |
| Range | 11.0 | 20.0 | -4.0 7.0 | 11.0 | 20.0 | -6.0 8.0 |
| 95 CI | | | -0.0 0.9 | | -0.3 0.6 | -0.0 0.6 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| N | | 82 | 82 | 82 | 82 | 164 |
| Mean | | 15.1 | 0.0 | 14.9 | -0.3 | 15.0 |
| SD | | 1.8 | 1.8 | 1.7 | 1.8 | 1.7 |
| Median | | 15.0 | 0.0 | 15.0 | 0.0 | 15.0 |
| Range | 10.0 | 19.0 | -4.0 6.0 | 11.0 | 18.0 | -5.0 6.0 |
| 95 CI | | | -0.4 0.4 | | -0.7 0.1 | -0.4 0.1 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| N | | 81 | 81 | 81 | 81 | 162 |
| Mean | | 15.0 | -0.1 | 14.7 | -0.5 | 14.8 |
| SD | | 1.6 | 1.8 | 1.7 | 1.9 | 1.7 |
| Median | | 15.0 | 0.0 | 15.0 | 0.0 | 15.0 |
| Range | 10.0 | 19.0 | -4.0 6.0 | 10.0 | 19.0 | -6.0 6.0 |
| 95 CI | | | -0.5 0.3 | | -0.9 -0.0 | -0.6 -0.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | |
| N | | 80 | 80 | 80 | 80 | 160 |
| Mean | | 14.6 | -0.5 | 14.5 | -0.6 | 14.6 |
| SD | | 1.6 | 1.9 | 1.6 | 2.0 | 1.6 |
| Median | | 15.0 | 0.0 | 14.5 | -1.0 | 15.0 |
| Range | 10.0 | 18.0 | -6.0 5.0 | 10.0 | 19.0 | -6.0 6.0 |
| 95 CI | | | -0.9 -0.0 | | -1.0 -0.2 | -0.8 -0.2 |

SAS program: P03_T06_01_02.sas - SAS dataset(s): RAND, SURGERY, INTRA_PRES

Table 6.1-3 (1 of 1): Intra ocular pressure - Point estimate of the difference between Treated vs. Non-treated eye Safety sample

| Visit | GEL (N=85) | EYE DROPS (N=83) | ALL (N=168) |
|--|---------------|---------------------|--------------------|
| V1 (before surgery) - (n %) | | | |
| N | 85 | 83 | 168 |
| Mean | 0.2 | 0.2 | 0.2 |
| SD | 1.4 | 1.4 | 1.4 |
| Median | 0.0 | 0.0 | 0.0 |
| Range | -4.0 | 6.0 | -5.0 4.0 -5.0 6.0 |
| V3 (day 1 after surgery) - (n %) | | | |
| N | 83 | 83 | 166 |
| Mean | 0.4 | 0.3 | 0.4 |
| SD | 2.7 | 1.6 | 2.2 |
| Median | 0.0 | 0.0 | 0.0 |
| Range | -6.0 | 18.0 | -5.0 5.0 -6.0 18.0 |
| V4 (day 7 after surgery) - (n %) | | | |
| N | 82 | 82 | 164 |
| Mean | -0.1 | -0.1 | -0.1 |
| SD | 1.5 | 1.5 | 1.5 |
| Median | 0.0 | 0.0 | 0.0 |
| Range | -6.0 | 5.0 | -6.0 5.0 -6.0 5.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | |
| N | 81 | 81 | 162 |
| Mean | -0.2 | 0.2 | -0.0 |
| SD | 1.7 | 1.2 | 1.5 |
| Median | 0.0 | 0.0 | 0.0 |
| Range | -8.0 | 4.0 | -2.0 4.0 -8.0 4.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | |
| N | 80 | 80 | 160 |
| Mean | -0.2 | 0.1 | -0.0 |
| SD | 1.0 | 1.1 | 1.1 |
| Median | 0.0 | 0.0 | 0.0 |
| Range | -5.0 | 3.0 | -2.0 4.0 -5.0 4.0 |

SAS program: P03_T06_01_03.sas - SAS dataset(s): RAND,SURGERY,INTRA_PRES

Note: difference computed as treated eye-non-treated eye

6.2 Ophthalmoscopy test

**Table 6.2-1 (1 of 1): Ophthalmoscopy test during the study - Frequency of test execution during the study
Safety sample**

| Visit | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| V1 (before surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| No | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 |
| Yes | 82 | 98.8 | 81 | 97.6 | 163 | 98.2 |
| Total | 83 | 100.0 | 83 | 100.0 | 166 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| No | 2 | 2.4 | 3 | 3.7 | 5 | 3.0 |
| Yes | 81 | 97.6 | 79 | 96.3 | 160 | 97.0 |
| Total | 83 | 100.0 | 82 | 100.0 | 165 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| No | 2 | 2.5 | 2 | 2.5 | 4 | 2.5 |
| Yes | 79 | 97.5 | 79 | 97.5 | 158 | 97.5 |
| Total | 81 | 100.0 | 81 | 100.0 | 162 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) (uncoded) | | | | | | |
| No | 0 | 0.0 | 1 | 1.2 | 1 | 0.6 |
| Yes | 2 | 2.5 | 2 | 2.5 | 4 | 2.5 |
| Total | 78 | 97.5 | 78 | 96.3 | 156 | 96.9 |
| | 80 | 100.0 | 81 | 100.0 | 161 | 100.0 |

SAS program: P03_T06_02_01.sas - SAS dataset(s):

Table 6.2-2-1 (1 of 1): Ophthalmoscopy test during the study - Frequency for Vitreous Safety sample

| Visit | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| V1 (before surgery) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Abnormal | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 82 | 100.0 | 81 | 100.0 | 163 | 100.0 |
| Abnormal | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 82 | 100.0 | 81 | 100.0 | 163 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 81 | 100.0 | 79 | 100.0 | 160 | 100.0 |
| Abnormal | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 81 | 100.0 | 79 | 100.0 | 160 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 79 | 100.0 | 79 | 100.0 | 158 | 100.0 |
| Abnormal | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 79 | 100.0 | 79 | 100.0 | 158 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 78 | 100.0 | 78 | 100.0 | 156 | 100.0 |
| Abnormal | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 78 | 100.0 | 78 | 100.0 | 156 | 100.0 |

SAS program: P03_T06_02_01.sas - SAS dataset(s): RAND,OPHTHALMOSCOPY

Table 6.2-2-2 (1 of 1): Ophthalmoscopy test during the study - Shift table for Vitreous Safety sample

| Before surgery | Day 1 | Day 7 | Day 15 | n | % | Cumulative frequency | | Missing (n) |
|------------------------|--------|--------|--------|----|--------|----------------------|--------|-------------|
| | | | | | | n | % | |
| GEL (N=85) | | | | | | | | |
| Normal | Normal | Normal | Normal | 79 | 100.00 | 79 | 100.00 | 6 |
| EYE DROPS(N=83) | | | | | | | | |
| Normal | Normal | Normal | Normal | 78 | 100.00 | 78 | 100.00 | 5 |

SAS program: P03_T06_02_02_02.sas - SAS dataset(s): RAND,OPHTHALMOSCOPY

Table 6.2-3-1 (1 of 1): Ophthalmoscopy test during the study - Frequency for Retina Safety sample

| Visit | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| V1 (before surgery) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 83 | 97.6 | 81 | 97.6 | 164 | 97.6 |
| Abnormal | 2 | 2.4 | 2 | 2.4 | 4 | 2.4 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 80 | 97.6 | 79 | 97.5 | 159 | 97.5 |
| Abnormal | 2 | 2.4 | 2 | 2.5 | 4 | 2.5 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 82 | 100.0 | 81 | 100.0 | 163 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 79 | 97.5 | 77 | 97.5 | 156 | 97.5 |
| Abnormal | 2 | 2.5 | 2 | 2.5 | 4 | 2.5 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 81 | 100.0 | 79 | 100.0 | 160 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 77 | 97.5 | 77 | 97.5 | 154 | 97.5 |
| Abnormal | 2 | 2.5 | 2 | 2.5 | 4 | 2.5 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 79 | 100.0 | 79 | 100.0 | 158 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | |
| Not done | 1 | 1.3 | 0 | 0.0 | 1 | 0.6 |
| Normal | 75 | 96.2 | 76 | 97.4 | 151 | 96.8 |
| Abnormal | 2 | 2.6 | 2 | 2.6 | 4 | 2.6 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 78 | 100.0 | 78 | 100.0 | 156 | 100.0 |

SAS program: P03_T06_02_03_01.sas - SAS dataset(s): RAND,OPHTHALMOSCOPY

Table 6.2-3-2 (1 of 2): Ophthalmoscopy test during the study - Shift table for Retina Safety sample

| Before surgery | Day 1 | Day 7 | Day 15 | n | % | Cumulative frequency | | Missing (n) |
|------------------------|----------|----------|----------|----|-------|----------------------|--------|-------------|
| | | | | | | n | % | |
| GEL (N=85) | | | | | | | | |
| Normal | Normal | Normal | Normal | 77 | 97.47 | 77 | 97.47 | 6 |
| Abnormal | Abnormal | Abnormal | Abnormal | 2 | 2.53 | 79 | 100.00 | |
| EYE DROPS(N=83) | | | | | | | | |
| Normal | Normal | Normal | Normal | 76 | 97.44 | 76 | 97.44 | 5 |
| Abnormal | Abnormal | Abnormal | Abnormal | 2 | 2.56 | 78 | 100.00 | |

SAS program: P03_T06_02_02.sas - SAS dataset(s): RAND,OPHTHALMOSCOPY

Table 6.2-4-1 (1 of 1): Ophthalmoscopy test during the study - Frequency for Macula Safety sample

| Visit | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| V1 (before surgery) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| Abnormal | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 82 | 100.0 | 81 | 100.0 | 163 | 100.0 |
| Abnormal | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 82 | 100.0 | 81 | 100.0 | 163 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 81 | 100.0 | 79 | 100.0 | 160 | 100.0 |
| Abnormal | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 81 | 100.0 | 79 | 100.0 | 160 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 79 | 100.0 | 79 | 100.0 | 158 | 100.0 |
| Abnormal | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 79 | 100.0 | 79 | 100.0 | 158 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 78 | 100.0 | 78 | 100.0 | 156 | 100.0 |
| Abnormal | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 78 | 100.0 | 78 | 100.0 | 156 | 100.0 |

SAS program: P03_T06_02_04_01.sas - SAS dataset(s): RAND,OPHTHALMOSCOPY

Table 6.2-4-2 (1 of 1): Ophthalmoscopy test during the study - Shift table for Macula Safety sample

| Before surgery | Day 1 | Day 7 | Day 15 | n | % | Cumulative frequency | | Missing (n) |
|-------------------------|--------|--------|--------|----|--------|----------------------|--------|-------------|
| | | | | | | n | % | |
| GEL (N=85) | | | | | | | | |
| Normal | Normal | Normal | Normal | 79 | 100.00 | 79 | 100.00 | 6 |
| EYE DROPS (N=83) | | | | | | | | |
| Normal | Normal | Normal | Normal | 78 | 100.00 | 78 | 100.00 | 5 |

SAS program: P03_T06_02_02_02.sas - SAS dataset(s): RAND,OPHTHALMOSCOPY

Table 6.2-5-1 (1 of 1): Ophthalmoscopy test during the study - Frequency for Choroid Safety sample

| Visit | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| V1 (before surgery) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 1 | 1.2 | 1 | 0.6 |
| Normal | 84 | 98.8 | 80 | 96.4 | 164 | 97.6 |
| Abnormal | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| Not done | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| Normal | 81 | 98.8 | 78 | 96.3 | 159 | 97.5 |
| Abnormal | 0 | 0.0 | 2 | 2.5 | 2 | 1.2 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 82 | 100.0 | 81 | 100.0 | 163 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Normal | 81 | 100.0 | 77 | 97.5 | 158 | 98.8 |
| Abnormal | 0 | 0.0 | 2 | 2.5 | 2 | 1.3 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 81 | 100.0 | 79 | 100.0 | 160 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| Not done | 0 | 0.0 | 1 | 1.3 | 1 | 0.6 |
| Normal | 79 | 100.0 | 76 | 96.2 | 155 | 98.1 |
| Abnormal | 0 | 0.0 | 2 | 2.5 | 2 | 1.3 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 79 | 100.0 | 79 | 100.0 | 158 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | |
| Not done | 1 | 1.3 | 0 | 0.0 | 1 | 0.6 |
| Normal | 77 | 98.7 | 75 | 96.2 | 152 | 97.4 |
| Abnormal | 0 | 0.0 | 3 | 3.8 | 3 | 1.9 |
| Not assessable | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Total | 78 | 100.0 | 78 | 100.0 | 156 | 100.0 |

SAS program: P03_T06_02_05_01.sas - SAS dataset(s): RAND,OPHTHALMOSCOPY

Table 6.2-5-2 (1 of 1): Ophthalmoscopy test during the study - Shift table for Choroid Safety sample

| Before surgery | Day 1 | Day 7 | Day 15 | n | % | Cumulative frequency | | Missing (n) |
|-------------------------|----------|----------|----------|----|-------|----------------------|--------|-------------|
| | | | | | | n | % | |
| GEL (N=85) | | | | | | | | |
| Normal | Normal | Normal | Normal | 78 | 98.73 | 78 | 98.73 | 6 |
| Abnormal | Normal | Normal | Normal | 1 | 1.27 | 79 | 100.00 | |
| EYE DROPS (N=83) | | | | | | | | |
| Not done | Not done | Normal | Normal | 1 | 1.28 | 1 | 1.28 | 5 |
| Normal | Normal | Normal | Not done | 1 | 1.28 | 2 | 2.56 | |
| Normal | Normal | Normal | Normal | 74 | 94.87 | 76 | 97.44 | |
| Abnormal | Abnormal | Abnormal | Abnormal | 2 | 2.56 | 78 | 100.00 | |

SAS program: P03_T06_02_02_02.sas - SAS dataset(s): RAND,OPHTHALMOSCOPY

6.3 Visual acuity

**Table 6.3-1 (1 of 1): Visual acuity during the study for the treated eye
Safety sample**

| Visit | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|------------|-----|-------------------|-----|-------------------|-----|
| | | | Change from Day 1 | | Change from Day 1 | |
| V1 (before surgery) - (n %) | | | | | | |
| N | 83 | | 82 | | 165 | |
| Mean | 0.5 | | 0.5 | | 0.5 | |
| SD | 0.2 | | 0.2 | | 0.2 | |
| Median | 0.5 | | 0.5 | | 0.5 | |
| Range | 0.0 | 1.0 | 0.0 | 1.0 | 0.0 | 1.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| N | 83 | | 82 | | 165 | |
| Mean | 0.6 | | 0.6 | | 0.6 | |
| SD | 0.4 | | 0.4 | | 0.4 | |
| Median | 0.8 | | 0.8 | | 0.8 | |
| Range | 0.0 | 1.0 | 0.0 | 1.3 | 0.0 | 1.3 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| N | 83 | 83 | 81 | 80 | 164 | 163 |
| Mean | 0.7 | 0.0 | 0.7 | 0.1 | 0.7 | 0.1 |
| SD | 0.4 | 0.1 | 0.5 | 0.3 | 0.4 | 0.2 |
| Median | 1.0 | 0.0 | 1.0 | 0.0 | 1.0 | 0.0 |
| Range | 0.0 | 1.2 | -0.2 | 0.5 | 0.0 | 2.0 |
| 95 CI | | 0.0 | 0.1 | | 0.0 | 0.1 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| N | 80 | 80 | 81 | 80 | 161 | 160 |
| Mean | 0.7 | 0.0 | 0.7 | 0.0 | 0.7 | 0.0 |
| SD | 0.4 | 0.1 | 0.4 | 0.2 | 0.4 | 0.1 |
| Median | 1.0 | 0.0 | 1.0 | 0.0 | 1.0 | 0.0 |
| Range | 0.0 | 1.2 | -0.2 | 0.5 | 0.0 | 1.3 |
| 95 CI | | 0.0 | 0.1 | | 0.0 | 0.1 |

SAS program: P03_T06_03_01.sas - SAS dataset(s): RAND, VISUAL_SCREEN, VISUAL_CONTROL

6.4 Ocular inflammation evalution

**Table 6.4-1 (1 of 1): Signs/Symptoms of ocular inflammation evaluation during the study - Frequency of test execution
Safety sample**

| Visit | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| V2 (surgery) - (n %) | | | | | | |
| No | 7 | 8.2 | 7 | 8.4 | 14 | 8.3 |
| Yes | 78 | 91.8 | 76 | 91.6 | 154 | 91.7 |
| Total | 85 | 100.0 | 83 | 100.0 | 168 | 100.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 83 | 100.0 | 83 | 100.0 | 166 | 100.0 |
| Total | 83 | 100.0 | 83 | 100.0 | 166 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| No | 1 | 1.2 | 0 | 0.0 | 1 | 0.6 |
| Yes | 82 | 98.8 | 82 | 100.0 | 164 | 99.4 |
| Total | 83 | 100.0 | 82 | 100.0 | 165 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| No | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Yes | 81 | 100.0 | 81 | 100.0 | 162 | 100.0 |
| Total | 81 | 100.0 | 81 | 100.0 | 162 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | |
| No | 2 | 2.5 | 1 | 1.2 | 3 | 1.9 |
| Yes | 78 | 97.5 | 79 | 97.5 | 157 | 97.5 |
| Total | 80 | 100.0 | 81 | 100.0 | 161 | 100.0 |

SAS program: P03_T06_04_01.sas - SAS dataset(s): RAND, OCULAR_INFRA

**Table 6.4-2 (1 of 1): Evaluation of ocular inflammation signs/symptoms during the study - Anterior chamber flare
Safety sample**

| Visit | GEL (N=85) | | | EYE DROPS (N=83) | | | ALL (N=168) | | | | | |
|---|-------------------|-------|-------------------|------------------|-------------------|-------|-------------------|-----------|-------------------|-------|-----|-------|
| | Change from day 1 | | Change from day 1 | | Change from day 1 | | Change from day 1 | | Change from day 1 | | | |
| | n | % | n | % | n | % | n | % | n | % | | |
| V2 (surgery) - (n %) | | | | | | | | | | | | |
| None | 57 | 73.1 | | | 54 | 71.1 | | | 111 | 72.1 | | |
| Mild | 21 | 26.9 | | | 22 | 28.9 | | | 43 | 27.9 | | |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Total | 78 | 100.0 | | | 76 | 100.0 | | | 154 | 100.0 | | |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | | | |
| None | 61 | 73.5 | | | 56 | 67.5 | | | 117 | 70.5 | | |
| Mild | 22 | 26.5 | | | 27 | 32.5 | | | 49 | 29.5 | | |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Total | 83 | 100.0 | | | 83 | 100.0 | | | 166 | 100.0 | | |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | | | |
| none | 77 | 93.9 | decreased | 17 | 20.7 | 79 | 96.3 | decreased | 24 | 29.3 | 156 | 95.1 |
| mild | 5 | 6.1 | unchanged | 65 | 79.3 | 3 | 3.7 | unchanged | 58 | 70.7 | 8 | 4.9 |
| moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 |
| severe | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 |
| total | 82 | 100.0 | | | 82 | 100.0 | | | 164 | 100.0 | | |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | | | |
| none | 81 | 100.0 | decreased | 21 | 25.9 | 81 | 100.0 | decreased | 27 | 33.3 | 162 | 100.0 |
| mild | 0 | 0.0 | unchanged | 60 | 74.1 | 0 | 0.0 | unchanged | 54 | 66.7 | 0 | 0.0 |
| moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 |
| severe | 0 | 0.0 | total | 81 | 100.0 | 0 | 0.0 | total | 81 | 100.0 | 0 | 0.0 |
| total | 81 | 100.0 | | | 81 | 100.0 | | | 162 | 100.0 | | |

SAS program: P03_T06_04_02.sas - SAS dataset(s): RAND, OCULAR_INFRA

**Table 6.4-3 (1 of 1): Evaluation of ocular inflammation signs/symptoms during the study - Anterior chamber cells
Safety sample**

| Visit | GEL (N=85) | | | EYE DROPS (N=83) | | | ALL (N=168) | | | | | |
|---|-------------------|-------|-----------|------------------|-------------------|-------|-------------|-----------|-------------------|-------|-----|------|
| | Change from Day 1 | | n | % | Change from Day 1 | | n | % | Change from Day 1 | | n | % |
| | n | % | n | % | n | % | n | % | n | % | n | % |
| V2 (surgery) - (n %) | | | | | | | | | | | | |
| None | 78 | 100.0 | | | 76 | 100.0 | | | 154 | 100.0 | | |
| Mild | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Total | 78 | 100.0 | | | 76 | 100.0 | | | 154 | 100.0 | | |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | | | |
| None | 75 | 90.4 | | | 77 | 92.8 | | | 152 | 91.6 | | |
| Mild | 8 | 9.6 | | | 6 | 7.2 | | | 14 | 8.4 | | |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Total | 83 | 100.0 | | | 83 | 100.0 | | | 166 | 100.0 | | |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | | | |
| none | 80 | 97.6 | decreased | 6 | 7.3 | 80 | 97.6 | decreased | 4 | 4.9 | 160 | 97.6 |
| mild | 2 | 2.4 | unchanged | 76 | 92.7 | 2 | 2.4 | unchanged | 77 | 93.9 | 4 | 2.4 |
| moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 1 | 1.2 | 0 | 0.0 |
| severe | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 |
| total | 82 | 100.0 | | | 82 | 100.0 | | | 164 | 100.0 | | |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | | | |
| none | 81 | 100.0 | decreased | 7 | 8.6 | 80 | 98.8 | decreased | 4 | 4.9 | 161 | 99.4 |
| mild | 0 | 0.0 | unchanged | 74 | 91.4 | 1 | 1.2 | unchanged | 77 | 95.1 | 1 | 0.6 |
| moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 |
| severe | 0 | 0.0 | total | 81 | 100.0 | 0 | 0.0 | total | 81 | 100.0 | 0 | 0.0 |
| total | 81 | 100.0 | | | 81 | 100.0 | | | 162 | 100.0 | | |

SAS program: P03_T06_04_03.sas - SAS dataset(s): RAND, OCULAR_INFRA

**Table 6.4-4 (1 of 1): Evaluation of ocular inflammation signs/symptoms during the study - Conjunctival hyperemia
Safety sample**

| Visit | GEL (N=85) | | | EYE DROPS (N=83) | | | ALL (N=168) | | | | | |
|---|-------------------|-------|-----------|------------------|-------------------|-------|-------------|-----------|-------------------|-------|-----|------|
| | Change from Day 1 | | n | % | Change from Day 1 | | n | % | Change from Day 1 | | n | % |
| | n | % | n | % | n | % | n | % | n | % | n | % |
| V2 (surgery) - (n %) | | | | | | | | | | | | |
| None | 71 | 91.0 | | | 73 | 96.1 | | | 144 | 93.5 | | |
| Mild | 7 | 9.0 | | | 3 | 3.9 | | | 10 | 6.5 | | |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Total | 78 | 100.0 | | | 76 | 100.0 | | | 154 | 100.0 | | |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | | | |
| None | 75 | 90.4 | | | 74 | 89.2 | | | 149 | 89.8 | | |
| Mild | 8 | 9.6 | | | 8 | 9.6 | | | 16 | 9.6 | | |
| Moderate | 0 | 0.0 | | | 1 | 1.2 | | | 1 | 0.6 | | |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Total | 83 | 100.0 | | | 83 | 100.0 | | | 166 | 100.0 | | |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | | | |
| none | 78 | 95.1 | decreased | 6 | 7.3 | 81 | 98.8 | decreased | 7 | 8.5 | 159 | 97.0 |
| mild | 4 | 4.9 | unchanged | 74 | 90.2 | 1 | 1.2 | unchanged | 75 | 91.5 | 5 | 3.0 |
| moderate | 0 | 0.0 | increased | 2 | 2.4 | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 |
| severe | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 |
| total | 82 | 100.0 | | | 82 | 100.0 | | | 164 | 100.0 | | |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | | | |
| none | 78 | 96.3 | decreased | 7 | 8.6 | 79 | 97.5 | decreased | 7 | 8.6 | 157 | 96.9 |
| mild | 3 | 3.7 | unchanged | 72 | 88.9 | 2 | 2.5 | unchanged | 73 | 90.1 | 5 | 3.1 |
| moderate | 0 | 0.0 | increased | 2 | 2.5 | 0 | 0.0 | increased | 1 | 1.2 | 0 | 0.0 |
| severe | 0 | 0.0 | total | 81 | 100.0 | 0 | 0.0 | total | 81 | 100.0 | 0 | 0.0 |
| total | 81 | 100.0 | | | 81 | 100.0 | | | 162 | 100.0 | | |

SAS program: P03_T06_04_04.sas - SAS dataset(s): RAND, OCULAR_INFRA

**Table 6.4-5 (1 of 1): Evaluation of ocular inflammation signs/symptoms during the study - Lid edema
Safety sample**

| Visit | GEL (N=85) | | | EYE DROPS (N=83) | | | ALL (N=168) | | | |
|---|-------------------|-------|-----------|------------------|-------------------|-------|-------------|-----------|-------------------|-------|
| | Change from Day 1 | | n | % | Change from Day 1 | | n | % | Change from Day 1 | |
| | n | % | n | % | n | % | n | % | n | % |
| V2 (surgery) - (n %) | | | | | | | | | | |
| None | 78 | 100.0 | | | 76 | 100.0 | | | 154 | 100.0 |
| Mild | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 78 | 100.0 | | | 76 | 100.0 | | | 154 | 100.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | |
| None | 83 | 100.0 | | | 83 | 100.0 | | | 166 | 100.0 |
| Mild | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 83 | 100.0 | | | 83 | 100.0 | | | 166 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | |
| none | 82 | 100.0 | decreased | 0 | 0.0 | 82 | 100.0 | decreased | 0 | 0.0 |
| mild | 0 | 0.0 | unchanged | 82 | 100.0 | 0 | 0.0 | unchanged | 82 | 100.0 |
| moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 |
| severe | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 | total | 82 | 100.0 |
| total | 82 | 100.0 | | | 82 | 100.0 | | | 164 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | |
| none | 81 | 100.0 | decreased | 0 | 0.0 | 81 | 100.0 | decreased | 0 | 0.0 |
| mild | 0 | 0.0 | unchanged | 81 | 100.0 | 0 | 0.0 | unchanged | 81 | 100.0 |
| moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 |
| severe | 0 | 0.0 | total | 81 | 100.0 | 0 | 0.0 | total | 81 | 100.0 |
| total | 81 | 100.0 | | | 81 | 100.0 | | | 162 | 100.0 |

SAS program: P03_T06_04_05.sas - SAS dataset(s): RAND, OCULAR_INFRA

**Table 6.4-6 (1 of 1): Evaluation of ocular inflammation signs/symptoms during the study - Corneal edema
Safety sample**

| Visit | GEL (N=85) | | | EYE DROPS (N=83) | | | ALL (N=168) | | | | | |
|---|-------------------|-------|-----------|------------------|-------------------|-------|-------------|-----------|-------------------|-------|-----|-------|
| | Change from Day 1 | | n | % | Change from Day 1 | | n | % | Change from Day 1 | | n | % |
| | n | % | n | % | n | % | n | % | n | % | n | % |
| V2 (surgery) - (n %) | | | | | | | | | | | | |
| None | 78 | 100.0 | | | 76 | 100.0 | | | 154 | 100.0 | | |
| Mild | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Total | 78 | 100.0 | | | 76 | 100.0 | | | 154 | 100.0 | | |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | | | |
| None | 80 | 96.4 | | | 81 | 97.6 | | | 161 | 97.0 | | |
| Mild | 3 | 3.6 | | | 0 | 0.0 | | | 3 | 1.8 | | |
| Moderate | 0 | 0.0 | | | 2 | 2.4 | | | 2 | 1.2 | | |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Total | 83 | 100.0 | | | 83 | 100.0 | | | 166 | 100.0 | | |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | | | |
| none | 82 | 100.0 | decreased | 3 | 3.7 | 82 | 100.0 | decreased | 1 | 1.2 | 164 | 100.0 |
| mild | 0 | 0.0 | unchanged | 79 | 96.3 | 0 | 0.0 | unchanged | 81 | 98.8 | 0 | 0.0 |
| moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 |
| severe | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 |
| total | 82 | 100.0 | | | 82 | 100.0 | | | 164 | 100.0 | | |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | | | |
| none | 81 | 100.0 | decreased | 2 | 2.5 | 81 | 100.0 | decreased | 1 | 1.2 | 162 | 100.0 |
| mild | 0 | 0.0 | unchanged | 79 | 97.5 | 0 | 0.0 | unchanged | 80 | 98.8 | 0 | 0.0 |
| moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 |
| severe | 0 | 0.0 | total | 81 | 100.0 | 0 | 0.0 | total | 81 | 100.0 | 0 | 0.0 |
| total | 81 | 100.0 | | | 81 | 100.0 | | | 162 | 100.0 | | |

SAS program: P03_T06_04_06.sas - SAS dataset(s): RAND, OCULAR_INFRA

**Table 6.4-7 (1 of 1): Evaluation of ocular inflammation signs/symptoms during the study - Ocular discomfort - Pain
Safety sample**

| Visit | GEL (N=85) | | | EYE DROPS (N=83) | | | ALL (N=168) | | | |
|---|-------------------|-------|-------------------|------------------|-------------------|-------|-------------------|-----------|-------------------|-------|
| | Change from Day 1 | | Change from Day 1 | | Change from Day 1 | | Change from Day 1 | | Change from Day 1 | |
| | n | % | n | % | n | % | n | % | n | % |
| V2 (surgery) - (n %) | | | | | | | | | | |
| None | 77 | 98.7 | | | 76 | 100.0 | | | 153 | 99.4 |
| Mild | 1 | 1.3 | | | 0 | 0.0 | | | 1 | 0.6 |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 78 | 100.0 | | | 76 | 100.0 | | | 154 | 100.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | |
| None | 82 | 98.8 | | | 81 | 97.6 | | | 163 | 98.2 |
| Mild | 1 | 1.2 | | | 1 | 1.2 | | | 2 | 1.2 |
| Moderate | 0 | 0.0 | | | 1 | 1.2 | | | 1 | 0.6 |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 83 | 100.0 | | | 83 | 100.0 | | | 166 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | |
| none | 82 | 100.0 | decreased | 1 | 1.2 | 82 | 100.0 | decreased | 1 | 1.2 |
| mild | 0 | 0.0 | unchanged | 81 | 98.8 | 0 | 0.0 | unchanged | 81 | 98.8 |
| moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 |
| severe | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 | total | 82 | 100.0 |
| total | 82 | 100.0 | | | 82 | 100.0 | | | 164 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | |
| none | 81 | 100.0 | decreased | 1 | 1.2 | 81 | 100.0 | decreased | 1 | 1.2 |
| mild | 0 | 0.0 | unchanged | 80 | 98.8 | 0 | 0.0 | unchanged | 80 | 98.8 |
| moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 |
| severe | 0 | 0.0 | total | 81 | 100.0 | 0 | 0.0 | total | 81 | 100.0 |
| total | 81 | 100.0 | | | 81 | 100.0 | | | 162 | 100.0 |
| V6 (follow-up at day 60 after surgery) - (n %) | | | | | | | | | | |
| none | 78 | 100.0 | decreased | 1 | 1.3 | 79 | 100.0 | decreased | 1 | 1.3 |
| mild | 0 | 0.0 | unchanged | 77 | 98.7 | 0 | 0.0 | unchanged | 78 | 98.7 |
| moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 |
| severe | 0 | 0.0 | total | 78 | 100.0 | 0 | 0.0 | total | 79 | 100.0 |
| total | 78 | 100.0 | | | 79 | 100.0 | | | 157 | 100.0 |

SAS program: P03_T06_04_07.sas - SAS dataset(s): RAND, OCULAR_INFLA

**Table 6.4-8 (1 of 1): Evaluation of ocular inflammation signs/symptoms during the study - Ocular discomfort - Photophobia
Safety sample**

| Visit | GEL (N=85) | | | EYE DROPS (N=83) | | | ALL (N=168) | | | |
|---|------------|-------|-------------------|------------------|-------|-------------------|-------------|-----------|-------------------|-------|
| | | | Change from Day 1 | | | Change from Day 1 | | | Change from Day 1 | |
| | n | % | n | % | n | % | n | % | n | |
| V2 (surgery) - (n %) | | | | | | | | | | |
| None | 69 | 88.5 | | | 67 | 88.2 | | | 136 | 88.3 |
| Mild | 9 | 11.5 | | | 9 | 11.8 | | | 18 | 11.7 |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 78 | 100.0 | | | 76 | 100.0 | | | 154 | 100.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | |
| None | 74 | 89.2 | | | 78 | 94.0 | | | 152 | 91.6 |
| Mild | 9 | 10.8 | | | 5 | 6.0 | | | 14 | 8.4 |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 83 | 100.0 | | | 83 | 100.0 | | | 166 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | |
| none | 79 | 96.3 | decreased | 7 | 8.5 | 81 | 98.8 | decreased | 4 | 4.9 |
| mild | 3 | 3.7 | unchanged | 74 | 90.2 | 1 | 1.2 | unchanged | 77 | 93.9 |
| moderate | 0 | 0.0 | increased | 1 | 1.2 | 0 | 0.0 | increased | 1 | 1.2 |
| severe | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 | total | 82 | 100.0 |
| total | 82 | 100.0 | | | 82 | 100.0 | | | 164 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | |
| none | 79 | 97.5 | decreased | 8 | 9.9 | 79 | 97.5 | decreased | 3 | 3.7 |
| mild | 2 | 2.5 | unchanged | 72 | 88.9 | 2 | 2.5 | unchanged | 77 | 95.1 |
| moderate | 0 | 0.0 | increased | 1 | 1.2 | 0 | 0.0 | increased | 1 | 1.2 |
| severe | 0 | 0.0 | total | 81 | 100.0 | 0 | 0.0 | total | 81 | 100.0 |
| total | 81 | 100.0 | | | 81 | 100.0 | | | 162 | 100.0 |

SAS program: P03_T06_04_08.sas - SAS dataset(s): RAND, OCULAR_INFRA

Table 6.4-9 (1 of 1): Evaluation of ocular inflammation signs/symptoms during the study - Ocular discomfort - Tearing Safety sample

| Visit | GEL (N=85) | | | EYE DROPS (N=83) | | | ALL (N=168) | | | |
|---|------------|-------|-------------------|------------------|-------|-------------------|-------------|-----------|-------------------|-------|
| | | | Change from Day 1 | | | Change from Day 1 | | | Change from Day 1 | |
| | n | % | n | % | n | % | n | % | n | |
| V2 (surgery) - (n %) | | | | | | | | | | |
| None | 68 | 87.2 | | | 69 | 90.8 | | | 137 | 89.0 |
| Mild | 10 | 12.8 | | | 7 | 9.2 | | | 17 | 11.0 |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 78 | 100.0 | | | 76 | 100.0 | | | 154 | 100.0 |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | |
| None | 73 | 88.0 | | | 76 | 91.6 | | | 149 | 89.8 |
| Mild | 10 | 12.0 | | | 7 | 8.4 | | | 17 | 10.2 |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 83 | 100.0 | | | 83 | 100.0 | | | 166 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | |
| none | 78 | 95.1 | decreased | 7 | 8.5 | 78 | 95.1 | decreased | 4 | 4.9 |
| mild | 4 | 4.9 | unchanged | 73 | 89.0 | 4 | 4.9 | unchanged | 76 | 92.7 |
| moderate | 0 | 0.0 | increased | 2 | 2.4 | 0 | 0.0 | increased | 2 | 2.4 |
| severe | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 | total | 82 | 100.0 |
| total | 82 | 100.0 | | | 82 | 100.0 | | | 164 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | |
| none | 76 | 93.8 | decreased | 9 | 11.1 | 77 | 95.1 | decreased | 4 | 4.9 |
| mild | 5 | 6.2 | unchanged | 68 | 84.0 | 4 | 4.9 | unchanged | 75 | 92.6 |
| moderate | 0 | 0.0 | increased | 4 | 4.9 | 0 | 0.0 | increased | 2 | 2.5 |
| severe | 0 | 0.0 | total | 81 | 100.0 | 0 | 0.0 | total | 81 | 100.0 |
| total | 81 | 100.0 | | | 81 | 100.0 | | | 162 | 100.0 |

SAS program: P03_T06_04_09.sas - SAS dataset(s): RAND, OCULAR_INFRA

**Table 6.4-10 (1 of 1): Evaluation of ocular inflammation signs/symptoms during the study - Total score
Safety sample**

| Visit | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|------------|------|-------------------|------|-------------------|------|
| | | | Change from Day 1 | | Change from Day 1 | |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| N | 83 | | 83 | | 166 | |
| Mean | 0.7 | | 0.7 | | 0.7 | |
| SD | 1.0 | | 1.3 | | 1.1 | |
| Median | 0.0 | | 0.0 | | 0.0 | |
| Range | 0.0 | 4.0 | 0.0 | 8.0 | 0.0 | 8.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| N | 82 | 82 | 82 | 82 | 164 | 164 |
| Mean | 0.2 | -0.5 | 0.1 | -0.5 | 0.2 | -0.5 |
| SD | 0.5 | 0.9 | 0.4 | 1.0 | 0.4 | 0.9 |
| Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Range | 0.0 | 2.0 | -4.0 | 1.0 | 0.0 | 2.0 |
| 95 CI | | | -0.7 | -0.3 | | |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| N | 81 | 81 | 81 | 81 | 162 | 162 |
| Mean | 0.1 | -0.6 | 0.1 | -0.6 | 0.1 | -0.6 |
| SD | 0.4 | 1.0 | 0.4 | 0.9 | 0.4 | 0.9 |
| Median | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Range | 0.0 | 2.0 | -4.0 | 2.0 | 0.0 | 2.0 |
| 95 CI | | | -0.8 | -0.4 | | |

SAS program: P03_T06_04_10.sas - SAS dataset(s): RAND, OCULAR_INFLA

Total score calculated as the sum of the single signs/symptoms

6.5 Global tolerability

**Table 6.5-1 (1 of 1): Evaluation of global tolerability by the investigator during the study - Frequency of test execution
Safety sample**

| Visit | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--|---------------|-------|---------------------|-------|----------------|-------|
| | n | % | n | % | n | % |
| V3 (day 1 after surgery) - (n %) | | | | | | |
| No | 0 | 0.0 | 1 | 1.2 | 1 | 0.6 |
| Yes | 83 | 100.0 | 82 | 98.8 | 165 | 99.4 |
| Total | 83 | 100.0 | 83 | 100.0 | 166 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | |
| No | 1 | 1.2 | 0 | 0.0 | 1 | 0.6 |
| Yes | 82 | 98.8 | 82 | 100.0 | 164 | 99.4 |
| Total | 83 | 100.0 | 82 | 100.0 | 165 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | |
| No | 1 | 1.2 | 0 | 0.0 | 1 | 0.6 |
| Yes | 80 | 98.8 | 81 | 100.0 | 161 | 99.4 |
| Total | 81 | 100.0 | 81 | 100.0 | 162 | 100.0 |

SAS program: P03_T06_05_01.sas - SAS dataset(s): RAND,TOLERABILITY

Table 6.5-2 (1 of 1): Evaluation of global tolerability by the investigator during the study - Burning Safety sample

| Visit | GEL (N=85) | | | EYE DROPS (N=83) | | | ALL (N=168) | | | |
|---|------------|-------|-------------------|------------------|-------|-------------------|-------------|-----------|-------------------|-------|
| | | | Change from day 1 | | | Change from day 1 | | | Change from day 1 | |
| | n | % | n | % | n | % | n | % | n | % |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | |
| None | 79 | 95.2 | | | 79 | 96.3 | | | 158 | 95.8 |
| Mild | 4 | 4.8 | | | 2 | 2.4 | | | 6 | 3.6 |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Severe | 0 | 0.0 | | | 1 | 1.2 | | | 1 | 0.6 |
| Total | 83 | 100.0 | | | 82 | 100.0 | | | 165 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | |
| none | 81 | 98.8 | decreased | 2 | 2.4 | 82 | 100.0 | decreased | 2 | 2.5 |
| mild | 1 | 1.2 | unchanged | 80 | 97.6 | 0 | 0.0 | unchanged | 79 | 97.5 |
| moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 |
| severe | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 | total | 81 | 100.0 |
| total | 82 | 100.0 | | | 82 | 100.0 | | | 164 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | |
| none | 80 | 100.0 | decreased | 3 | 3.8 | 81 | 100.0 | decreased | 2 | 2.5 |
| mild | 0 | 0.0 | unchanged | 77 | 96.3 | 0 | 0.0 | unchanged | 78 | 97.5 |
| moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 |
| severe | 0 | 0.0 | total | 80 | 100.0 | 0 | 0.0 | total | 80 | 100.0 |
| total | 80 | 100.0 | | | 81 | 100.0 | | | 161 | 100.0 |

SAS program: P03_T06_05_02.sas - SAS dataset(s): RAND,TOLERABILITY

Table 6.5-3 (1 of 1): Evaluation of global tolerability by the investigator during the study - Stinging Safety sample

| Visit | GEL (N=85) | | | EYE DROPS (N=83) | | | ALL (N=168) | | | | | | | | |
|---|------------|-------|-------------------|------------------|-------|-------------------|-------------|-----------|-------------------|-------|-----|------|-----------|-----|-------|
| | | | Change from day 1 | | | Change from day 1 | | | Change from day 1 | | | | | | |
| | n | % | n | % | n | % | n | % | n | % | | | | | |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | | | | | | |
| None | 75 | 90.4 | | | 75 | 91.5 | | | 150 | 90.9 | | | | | |
| Mild | 7 | 8.4 | | | 6 | 7.3 | | | 13 | 7.9 | | | | | |
| Moderate | 1 | 1.2 | | | 0 | 0.0 | | | 1 | 0.6 | | | | | |
| Severe | 0 | 0.0 | | | 1 | 1.2 | | | 1 | 0.6 | | | | | |
| Total | 83 | 100.0 | | | 82 | 100.0 | | | 165 | 100.0 | | | | | |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | | | | | | |
| none | 77 | 93.9 | decreased | 4 | 4.9 | 77 | 93.9 | decreased | 3 | 3.7 | 154 | 93.9 | decreased | 7 | 4.3 |
| mild | 5 | 6.1 | unchanged | 77 | 93.9 | 5 | 6.1 | unchanged | 76 | 93.8 | 10 | 6.1 | unchanged | 153 | 93.9 |
| moderate | 0 | 0.0 | increased | 1 | 1.2 | 0 | 0.0 | increased | 2 | 2.5 | 0 | 0.0 | increased | 3 | 1.8 |
| severe | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 | total | 81 | 100.0 | 0 | 0.0 | total | 163 | 100.0 |
| total | 82 | 100.0 | | | 82 | 100.0 | | | 164 | 100.0 | | | | | |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | | | | | | |
| none | 76 | 95.0 | decreased | 5 | 6.3 | 77 | 95.1 | decreased | 3 | 3.8 | 153 | 95.0 | decreased | 8 | 5.0 |
| mild | 4 | 5.0 | unchanged | 73 | 91.3 | 4 | 4.9 | unchanged | 76 | 95.0 | 8 | 5.0 | unchanged | 149 | 93.1 |
| moderate | 0 | 0.0 | increased | 2 | 2.5 | 0 | 0.0 | increased | 1 | 1.3 | 0 | 0.0 | increased | 3 | 1.9 |
| severe | 0 | 0.0 | total | 80 | 100.0 | 0 | 0.0 | total | 80 | 100.0 | 0 | 0.0 | total | 160 | 100.0 |
| total | 80 | 100.0 | | | 81 | 100.0 | | | 161 | 100.0 | | | | | |

SAS program: P03_T06_05_03.sas - SAS dataset(s): RAND,TOLERABILITY

**Table 6.5-4 (1 of 1): Evaluation of global tolerability by the investigator during the study - Blurred vision
Safety sample**

| Visit | GEL (N=85) | | | EYE DROPS (N=83) | | | ALL (N=168) | | | |
|---|-------------------|-------|-------------------|------------------|-------------------|-------|-------------------|-----------|-------------------|-------|
| | Change from day 1 | | Change from day 1 | | Change from day 1 | | Change from day 1 | | Change from day 1 | |
| | n | % | n | % | n | % | n | % | n | % |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | |
| None | 80 | 96.4 | | | 81 | 98.8 | | | 161 | 97.6 |
| Mild | 1 | 1.2 | | | 1 | 1.2 | | | 2 | 1.2 |
| Moderate | 2 | 2.4 | | | 0 | 0.0 | | | 2 | 1.2 |
| Severe | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 |
| Total | 83 | 100.0 | | | 82 | 100.0 | | | 165 | 100.0 |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | |
| none | 77 | 93.9 | decreased | 1 | 1.2 | 80 | 97.6 | decreased | 0 | 0.0 |
| mild | 4 | 4.9 | unchanged | 78 | 95.1 | 2 | 2.4 | unchanged | 79 | 97.5 |
| moderate | 1 | 1.2 | increased | 3 | 3.7 | 0 | 0.0 | increased | 2 | 2.5 |
| severe | 0 | 0.0 | total | 82 | 100.0 | 0 | 0.0 | total | 81 | 100.0 |
| total | 82 | 100.0 | | | 82 | 100.0 | | | 164 | 100.0 |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | |
| none | 78 | 97.5 | decreased | 2 | 2.5 | 78 | 96.3 | decreased | 0 | 0.0 |
| mild | 1 | 1.3 | unchanged | 76 | 95.0 | 3 | 3.7 | unchanged | 77 | 96.3 |
| moderate | 0 | 0.0 | increased | 2 | 2.5 | 0 | 0.0 | increased | 3 | 3.8 |
| severe | 1 | 1.3 | total | 80 | 100.0 | 0 | 0.0 | total | 80 | 100.0 |
| total | 80 | 100.0 | | | 81 | 100.0 | | | 161 | 100.0 |

SAS program: P03_T06_05_04.sas - SAS dataset(s): RAND,TOLERABILITY

**Table 6.5-5 (1 of 1): Evaluation of global tolerability by the investigator during the study - Global subjective tolerability
Safety sample**

| Visit | GEL (N=85) | | | EYE DROPS (N=83) | | | ALL (N=168) | | | | | |
|---|-------------------|-------|-------------------|------------------|-------------------|-------|-------------------|-----------|-------------------|-------|-----|-------|
| | Change from day 1 | | Change from day 1 | | Change from day 1 | | Change from day 1 | | Change from day 1 | | | |
| | n | % | n | % | n | % | n | % | n | % | | |
| V3 (day 1 after surgery) - (n %) | | | | | | | | | | | | |
| None | 81 | 97.6 | | | 81 | 98.8 | | | 162 | 98.2 | | |
| Mild | 2 | 2.4 | | | 0 | 0.0 | | | 2 | 1.2 | | |
| Moderate | 0 | 0.0 | | | 0 | 0.0 | | | 0 | 0.0 | | |
| Severe | 0 | 0.0 | | | 1 | 1.2 | | | 1 | 0.6 | | |
| Total | 83 | 100.0 | | | 82 | 100.0 | | | 165 | 100.0 | | |
| V4 (day 7 after surgery) - (n %) | | | | | | | | | | | | |
| none | 82 | 100.0 | decreased | 1 | 1.2 | 82 | 100.0 | decreased | 0 | 0.0 | 164 | 100.0 |
| mild | 0 | 0.0 | unchanged | 81 | 98.8 | 0 | 0.0 | unchanged | 81 | 100.0 | 0 | 0.0 |
| moderate | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 | increased | 0 | 0.0 | 0 | 0.0 |
| severe | 0 | 0.0 | total | 0 | 0.0 | 0 | 0.0 | total | 0 | 0.0 | 0 | 0.0 |
| total | 82 | 100.0 | | | 82 | 100.0 | | | 164 | 100.0 | | |
| V5 (day 15 after surgery - end of treatment) - (n %) | | | | | | | | | | | | |
| none | 79 | 98.8 | decreased | 1 | 1.3 | 80 | 98.8 | decreased | 0 | 0.0 | 159 | 98.8 |
| mild | 0 | 0.0 | unchanged | 78 | 97.5 | 1 | 1.2 | unchanged | 79 | 98.8 | 1 | 0.6 |
| moderate | 1 | 1.3 | increased | 1 | 1.3 | 0 | 0.0 | increased | 1 | 1.3 | 1 | 0.6 |
| severe | 0 | 0.0 | total | 80 | 100.0 | 0 | 0.0 | total | 80 | 100.0 | 0 | 0.0 |
| total | 80 | 100.0 | | | 81 | 100.0 | | | 161 | 100.0 | | |

SAS program: P03_T06_05_05.sas - SAS dataset(s): RAND,TOLERABILITY

6.6 Adverse events

**Table 6.6-1 (1 of 1): Overview of Adverse Events
Safety sample**

| Variable | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|---|---------------|-----|---------------------|-----|----------------|-----|
| | n | % | n | % | n | % |
| All AEs | 4 | 4.7 | 6 | 7.2 | 10 | 6.0 |
| SAE | . | . | 2 | 2.4 | 2 | 1.2 |
| AE related to study drug | . | . | 1 | 1.2 | 1 | 0.6 |
| AE leading to discontinuation of study drug | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |

Source: on-line editing

[1] Related=Relationship of Possibly, Probably or Definitely Related, as noted by investigator on the eCRF.

**Table 6.6-2 (1 of 1): Summary of all Adverse Events by MedDRA System Organ Class and Preferred Term
Safety sample**

| System Organ Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--|---------------|-----|---------------------|-----|----------------|-----|
| | n | % | n | % | n | % |
| Subjects with at least one event | 4 | 4.7 | 6 | 7.2 | 10 | 6.0 |
| Eye disorders | 1 | 1.2 | 3 | 3.6 | 4 | 2.4 |
| Conjunctival hyperaemia | . | . | 1 | 1.2 | 1 | 0.6 |
| Foreign body sensation in eyes | 1 | 1.2 | 2 | 2.4 | 3 | 1.8 |
| Macular oedema | . | . | 1 | 1.2 | 1 | 0.6 |
| Gastrointestinal disorders | 1 | 1.2 | . | . | 1 | 0.6 |
| Dyspepsia | 1 | 1.2 | . | . | 1 | 0.6 |
| Nausea | 1 | 1.2 | . | . | 1 | 0.6 |
| Immune system disorders | . | . | 1 | 1.2 | 1 | 0.6 |
| Drug hypersensitivity | . | . | 1 | 1.2 | 1 | 0.6 |
| Infections and infestations | . | . | 1 | 1.2 | 1 | 0.6 |
| Hordeolum | . | . | 1 | 1.2 | 1 | 0.6 |
| Injury, poisoning and procedural complications | 1 | 1.2 | . | . | 1 | 0.6 |
| Fibrin deposition on lens postoperative | 1 | 1.2 | . | . | 1 | 0.6 |
| Investigations | 3 | 3.5 | . | . | 3 | 1.8 |
| Blood pressure increased | 1 | 1.2 | . | . | 1 | 0.6 |
| Intraocular pressure increased | 3 | 3.5 | . | . | 3 | 1.8 |
| Vascular disorders | . | . | 1 | 1.2 | 1 | 0.6 |
| Vascular occlusion | . | . | 1 | 1.2 | 1 | 0.6 |

SAS program: P03_T06_06_02.sas - SAS dataset(s): RAND,AE_COD

Notes:

- A subject with multiple occurrences is counted only once in the respective category.
- Table is sorted alphabetically
- Within system organ class, AEs are sorted by descending frequency of preferred term

Listing of patients with System Organ Class equal to *Investigations - Safety sample*

| Subj. code | Reported term | Start date | End date | SAE Severity | Study drug relat. | Action taken | Other action taken | Outcome |
|---------------|---|---------------|-----------|--------------|-------------------------|-----------------|--|---------------------|
| GEL | | | | | | | | |
| 200101 | HIGH IOP (LA 34MMHG) | 17JAN2018 | 18JAN2018 | NO MILD | UNRELATED | NONE | CONCOMITANT THERAPY | COMPLETELY RECOVERY |
| 200111 | INCREASED IOP | 06NOV2018 | 07NOV2018 | NO MODERATE | UNRELATED | NONE | CONCOMITANT THERAPY ADDITIONAL EYE DROPS TO LOWER DOWN THE IOP | COMPLETELY RECOVERY |
| 200203 | HIGH INTRAOCULAR PRESSURE (POSTOPERATIVE) | 26JUN2018 | 27JUN2018 | NO MILD | UNLIKELY | NONE | CONCOMITANT THERAPY TOPICAL ADMINISTRATTION OF COSOPT D GTT | COMPLETELY RECOVERY |
| | INCREASE OF BLOOD PRESSURE | 23AUG2018 | 25AUG2018 | NO MILD | UNLIKELY | NONE | CONCOMITANT THERAPY | COMPLETELY RECOVERY |

Listing produced from SAS program P03_T06_06_02.sas - SAS dataset(s): RAND,AE_COD

**Table 6.6-3 (1 of 1): Summary of Serious Adverse Events, by MedDRA System Organ Class and Preferred Term
Safety sample**

| System Organ Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--------------------------------------|---------------|---|---------------------|-----|----------------|-----|
| | n | % | n | % | n | % |
| Subjects with at least one event | . | . | 1 | 1.2 | 1 | 0.6 |
| Eye disorders | . | . | 1 | 1.2 | 1 | 0.6 |
| Macular oedema | . | . | 1 | 1.2 | 1 | 0.6 |
| Vascular disorders | . | . | 1 | 1.2 | 1 | 0.6 |
| Vascular occlusion | . | . | 1 | 1.2 | 1 | 0.6 |

SAS program: P03_T06_06_03.sas - SAS dataset(s): RAND,AE_CODE

Notes:

- A subject with multiple occurrences is counted only once in the respective category.
- Table is sorted alphabetically
- Within system organ class, AEs are sorted by descending frequency of preferred term

**Table 6.6-4 (1 of 1): Summary of Related Adverse Events, by MedDRA System Organ Class and Preferred Term
Safety sample**

| System Organ Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--------------------------------------|---------------|---|---------------------|-----|----------------|-----|
| | n | % | n | % | n | % |
| Subjects with at least one event | . | . | 1 | 1.2 | 1 | 0.6 |
| Immune system disorders | . | . | 1 | 1.2 | 1 | 0.6 |
| Drug hypersensitivity | . | . | 1 | 1.2 | 1 | 0.6 |

SAS program: P03_T06_06_04.sas - SAS dataset(s): RAND,AE_CODE

Notes:

- A subject with multiple occurrences is counted only once in the respective category.
- Table is sorted alphabetically
- Within system organ class, AEs are sorted by descending frequency of preferred term
- AEs considered in this table are the event Possibly/Probably/Definitely related with study drug

Table 6.6-5 (1 of 1): Summary of Adverse Events leading to discontinuation, by MedDRA System Organ Class and Preferred Term Safety sample

| System Organ Class Preferred term | GEL (N=85) | | EYE DROPS (N=83) | | ALL (N=168) | |
|--|---------------|-----|---------------------|-----|----------------|-----|
| | n | % | n | % | n | % |
| Subjects with at least one event | 1 | 1.2 | 1 | 1.2 | 2 | 1.2 |
| Immune system disorders | . | . | 1 | 1.2 | 1 | 0.6 |
| Drug hypersensitivity | . | . | 1 | 1.2 | 1 | 0.6 |
| Injury, poisoning and procedural complications | 1 | 1.2 | . | . | 1 | 0.6 |
| Fibrin deposition on lens postoperative | 1 | 1.2 | . | . | 1 | 0.6 |

SAS program: P03_T06_06_05.sas - SAS dataset(s): RAND,AE_COD

Notes:

- A subject with multiple occurrences is counted only once in the respective category.
- Table is sorted alphabetically
- Within system organ class, AEs are sorted by descending frequency of preferred term

Appendix 2: Individual patient listing

| | Page |
|------------|---|
| Listing 1 | Patient information/ Registration |
| Listing 2 | Eligibility criteria |
| Listing 3 | Screening visit – Pregnancy test |
| Listing 4 | Screening visit – Amsler and OCT tests at study entry |
| Listing 5 | Screening visit – General and Ophthalmic medical history at study entry |
| Listing 6 | Visual acuity, Intra-ocular pressure and Slit lamp examination during the study |
| Listing 7 | Ophthalmoscopic test during the study |
| Listing 8 | Bromfenac treatment before surgery, Ocular surface sterilization and Surgery problems |
| Listing 9 | Mydriatic drugs and Antibiotic treatments before surgery |
| Listing 10 | Antibiotic treatments after surgery |
| Listing 11 | Study treatment after surgery |
| Listing 12 | Signs/Symptoms of ocular inflammation during the study |
| Listing 13 | Microbial load during the study |
| Listing 14 | Evaluation of global tolerability by the investigator during the study |
| Listing 15 | End of study |
| Listing 16 | Concomitant treatments |
| Listing 17 | Adverse event |
| Listing 18 | Unscheduled visit |

Note: all listings report under Study drug column:

GEL for NETILDEX 3mg/mL / 1mg/mL ophthalmic gel

DROP for NETILDEX 3mg/mL / 1mg/mL eye drops solutions

Listing 1 (1 of 9): Patient Information/ Registration

| Sbj Code | Date of birth | Age* (yrs) | Sex | If Race=Other, Race specify | Randomiz. Number | Study Drug |
|-------------|------------------|---------------|--------|--------------------------------|---------------------|---------------|
| 100101 | 03MAY1933 | 84 | Female | White | 10001 | DROP |
| 100102 | 14MAY1937 | 80 | Male | White | 10002 | GEL |
| 100103 | 07AUG1947 | 70 | Female | White | | |
| 100104 | 06FEB1947 | 70 | Male | White | 10003 | GEL |
| 100105 | 19MAY1932 | 85 | Female | White | 10004 | DROP |
| 100106 | 14JAN1961 | 56 | Male | White | 10005 | GEL |
| 100107 | 24AUG1935 | 82 | Female | White | 10006 | DROP |
| 100108 | 23JAN1944 | 73 | Female | White | 10007 | DROP |
| 100109 | 29SEP1961 | 56 | Female | White | 10008 | GEL |
| 100110 | 01JUL1942 | 75 | Female | White | 10009 | DROP |
| 100111 | 04FEB1957 | 60 | Female | White | 10010 | DROP |
| 100112 | 23JUN1944 | 73 | Male | White | 10011 | GEL |
| 100113 | 01JUN1940 | 77 | Female | White | 10012 | GEL |
| 100114 | 03FEB1953 | 64 | Male | White | 10013 | GEL |
| 100115 | 05FEB1941 | 76 | Male | White | 10014 | DROP |
| 100116 | 14FEB1955 | 62 | Male | White | 10015 | GEL |
| 100117 | 31MAY1967 | 51 | Female | White | 10016 | DROP |
| 100118 | 28OCT1940 | 78 | Female | White | 10017 | DROP |
| 100119 | 21NOV1946 | 72 | Female | White | 10018 | DROP |
| 100120 | 14MAY1939 | 79 | Male | White | 10019 | GEL |
| 100121 | 21JAN1938 | 80 | Male | White | 10020 | GEL |
| 100122 | 19OCT1942 | 76 | Female | White | 10021 | DROP |

Listing 1 (2 of 9): Patient Information/ Registration

| Sbj Code | Date of birth | Age* (yrs) | Sex | If Race=Other, Race specify | Randomiz. Number | Study Drug |
|-------------|------------------|---------------|--------|--------------------------------|---------------------|---------------|
| 100123 | 19OCT1942 | 76 | Female | White | 10022 | DROP |
| 100124 | 29JUL1947 | 71 | Female | White | 10023 | GEL |
| 100125 | 05APR1956 | 62 | Female | White | 10024 | GEL |
| 100126 | 25JAN1933 | 85 | Female | White | 10025 | GEL |
| 100127 | 23NOV1950 | 68 | Female | White | 10026 | GEL |
| 100128 | 15SEP1938 | 80 | Male | White | 10027 | DROP |
| 100129 | 28FEB1940 | 78 | Female | White | 10028 | DROP |
| 100130 | 28MAR1952 | 66 | Male | White | 10029 | GEL |
| 100131 | 05JUN1941 | 77 | Female | White | 10030 | DROP |
| 100132 | 16NOV1949 | 69 | Male | White | 10031 | DROP |
| 100133 | 02JAN1944 | 74 | Male | White | 10032 | GEL |
| 100134 | 12JUN1952 | 66 | Female | White | 10033 | DROP |
| 100135 | 11JUL1949 | 69 | Male | White | 10034 | GEL |
| 100136 | 24NOV1928 | 90 | Female | White | 10035 | GEL |
| 100137 | 27JAN1956 | 62 | Female | White | 10036 | DROP |
| 100138 | 16MAY1955 | 63 | Male | White | 10037 | GEL |
| 100139 | 29OCT1947 | 71 | Female | White | 10038 | DROP |
| 100140 | 02APR1937 | 81 | Male | White | 10039 | GEL |
| 100141 | 08FEB1944 | 74 | Female | White | 10040 | DROP |
| 100142 | 15JAN1941 | 77 | Female | White | 10041 | GEL |
| 100143 | 25FEB1944 | 74 | Male | White | 10042 | GEL |
| 100144 | 08FEB1929 | 89 | Female | White | 10043 | DROP |

Listing 1 (3 of 9): Patient Information/ Registration

| Sbj Code | Date of birth | Age* (yrs) | Sex | If Race=Other, Race specify | Randomiz. Number | Study Drug |
|-------------|------------------|---------------|--------|--------------------------------|---------------------|---------------|
| 100145 | 29AUG1937 | 81 | Male | White | 10044 | GEL |
| 100146 | 17FEB1947 | 71 | Male | White | 10045 | GEL |
| 100147 | 25AUG1970 | 48 | Male | White | 10046 | DROP |
| 100148 | 13MAY1935 | 83 | Female | White | 10047 | DROP |
| 100149 | 07FEB1947 | 71 | Female | White | 10048 | DROP |
| 100150 | 09MAY1941 | 77 | Female | White | 100049 | GEL |
| 100151 | 15AUG1951 | 67 | Female | White | 100050 | DROP |
| 100152 | 26APR1940 | 78 | Female | White | 100051 | GEL |
| 100153 | 18JAN1937 | 81 | Female | White | 100052 | DROP |
| 100154 | 07NOV1950 | 68 | Female | White | 100053 | GEL |
| 100155 | 01FEB1939 | 79 | Female | White | 100054 | DROP |
| 100156 | 06JAN1949 | 69 | Female | White | 100055 | GEL |
| 100201 | 19MAY1937 | 80 | Female | White | 200-01 | GEL |
| 100202 | 19JUN1947 | 70 | Female | White | 200-02 | DROP |
| 100203 | 16MAR1941 | 76 | Female | White | 200-03 | DROP |
| 100204 | 13JUN1946 | 71 | Male | White | 200-04 | GEL |
| 100205 | 12AUG1942 | 75 | Male | White | 200-05 | GEL |
| 100206 | 13JUL1937 | 81 | Female | White | 200-06 | DROP |
| 100207 | 08APR1953 | 65 | Female | White | 200-07 | DROP |
| 100208 | 09FEB1939 | 79 | Female | White | 200-08 | GEL |
| 100209 | 14MAR1941 | 77 | Female | White | 200-09 | GEL |
| 100210 | 15MAR1948 | 70 | Female | White | 200-10 | DROP |

Listing 1 (4 of 9): Patient Information/ Registration

| Sbj Code | Date of birth | Age* (yrs) | Sex | If Race=Other, Race specify | Randomiz. Number | Study Drug |
|-------------|------------------|---------------|--------|--------------------------------|---------------------|---------------|
| 100211 | 04NOV1951 | 67 | Male | White | 200-11 | GEL |
| 100212 | 30APR1936 | 82 | Female | White | 200-12 | DROP |
| 100213 | 09APR1937 | 81 | Female | White | 200-13 | DROP |
| 100214 | 17NOV1941 | 77 | Female | White | 20014 | DROP |
| 100215 | 21JUL1935 | 83 | Female | White | 200-15 | GEL |
| 100216 | 04NOV1944 | 74 | Female | White | 20016 | GEL |
| 100217 | 16FEB1946 | 72 | Female | White | 20017 | DROP |
| 100218 | 02AUG1946 | 72 | Male | White | 20018 | DROP |
| 100219 | 12APR1935 | 83 | Female | White | 20019 | GEL |
| 100220 | 05DEC1954 | 64 | Male | White | 20020 | GEL |
| 100221 | 15NOV1942 | 76 | Female | White | 20021 | GEL |
| 100222 | 01JUN1942 | 76 | Female | White | 20022 | DROP |
| 100223 | 02SEP1957 | 61 | Male | White | 20023 | DROP |
| 100224 | 14MAY1943 | 75 | Female | White | 20024 | GEL |
| 100225 | 09JAN1939 | 79 | Female | White | 20025 | DROP |
| 100226 | 09SEP1944 | 74 | Female | White | 20026 | GEL |
| 100227 | 08SEP1950 | 68 | Female | White | 20027 | DROP |
| 100228 | 15APR1950 | 68 | Female | White | 20028 | GEL |
| 100229 | 06SEP1948 | 70 | Female | White | 20029 | GEL |
| 100230 | 21SEP1955 | 63 | Female | White | 20030 | GEL |
| 100231 | 06OCT1944 | 74 | Female | White | 20031 | DROP |
| 100232 | 06DEC1945 | 73 | Female | White | 20032 | DROP |

Listing 1 (5 of 9): Patient Information/ Registration

| Sbj Code | Date of birth | Age* (yrs) | Sex | If Race=Other, Race specify | Randomiz. Number | Study Drug |
|-------------|------------------|---------------|--------|--------------------------------|--------------------------|---------------|
| 100233 | 16NOV1946 | 72 | Female | White | 20033 | GEL |
| 100234 | 17DEC1945 | 73 | Female | White | 20034 | GEL |
| 100235 | 13MAY1954 | 64 | Male | White | 20035 | DROP |
| 100236 | 20DEC1948 | 70 | Female | White | 20036 | DROP |
| 100237 | 22NOV1945 | 73 | Male | White | 20037 | DROP |
| 100238 | 14JAN1940 | 78 | Male | White | 20038 | GEL |
| 100239 | 21AUG1938 | 80 | Female | White | 20039 | DROP |
| 100240 | 26APR1946 | 72 | Female | White | no treatment assigned | |
| 100241 | 15APR1944 | 74 | Female | White | 20040 | GEL |
| 100242 | 16FEB1951 | 67 | Female | White | 200-41 | GEL |
| 100243 | 04OCT1944 | 74 | Male | White | 20042 | DROP |
| 100244 | 12FEB1952 | 66 | Female | White | 20043 | GEL |
| 100245 | 23SEP1949 | 69 | Female | Black | 20044 | DROP |
| 100301 | 18JUL1949 | 68 | Female | White | 30001 | GEL |
| 100302 | 03APR1956 | 61 | Male | White | 3002 | GEL |
| 100303 | 06MAY1944 | 73 | Female | White | 30003 | DROP |
| 100304 | 22DEC1959 | 58 | Male | Black | 30004 | DROP |
| 100305 | 05JAN1932 | 85 | Female | White | 30005 | DROP |
| 100306 | 07JUL1933 | 84 | Female | White | 30006 | DROP |
| 100307 | 05DEC1944 | 73 | Female | White | 30007 | GEL |
| 100308 | 15MAR1932 | 85 | Female | White | 30008 | GEL |
| 100309 | 03SEP1956 | 61 | Female | White | 30009 | DROP |

Listing 1 (6 of 9): Patient Information/ Registration

| Sbj Code | Date of birth | Age* (yrs) | Sex | If Race=Other, Race specify | Randomiz. Number | Study Drug |
|-------------|------------------|---------------|--------|--------------------------------|---------------------|---------------|
| 100310 | 20MAR1944 | 73 | Female | White | 30010 | GEL |
| 100311 | 10OCT1934 | 83 | Female | White | 300011 | GEL |
| 100312 | 01DEC1946 | 71 | Female | White | 300012 | DROP |
| 100313 | 26APR1946 | 71 | Male | White | 30013 | GEL |
| 100314 | 19APR1950 | 67 | Male | White | 30014 | DROP |
| 100315 | 11JUL1952 | 65 | Female | White | 30015 | GEL |
| 100316 | 29SEP1941 | 76 | Male | White | 30016 | DROP |
| 100317 | 12JAN1932 | 85 | Male | White | 30017 | GEL |
| 100318 | 22MAR1937 | 80 | Female | White | 30018 | GEL |
| 100319 | 23MAR1947 | 70 | Male | White | 30019 | DROP |
| 100320 | 01APR1948 | 69 | Male | White | 30020 | DROP |
| 100321 | 13MAR1945 | 72 | Male | White | 30021 | GEL |
| 100322 | 15OCT1937 | 80 | Male | White | 30022 | GEL |
| 100323 | 29JUN1941 | 76 | Female | White | 30023 | DROP |
| 100324 | 11JUN1952 | 65 | Male | White | 30024 | DROP |
| 100325 | 20MAY1934 | 83 | Female | White | 30025 | GEL |
| 100326 | 16DEC1936 | 81 | Male | White | 30026 | DROP |
| 100327 | 11FEB1944 | 73 | Female | White | 30027 | GEL |
| 100328 | 04FEB1935 | 82 | Male | White | 30028 | DROP |
| 100329 | 11MAR1943 | 74 | Male | White | 30029 | GEL |
| 100330 | 07MAY1956 | 61 | Male | White | 30030 | DROP |
| 100331 | 30OCT1946 | 71 | Female | White | 30031 | GEL |

Listing 1 (7 of 9): Patient Information/ Registration

| Sbj Code | Date of birth | Age* (yrs) | Sex | If Race=Other, Race specify | Randomiz. Number | Study Drug |
|-------------|------------------|---------------|--------|--------------------------------|---------------------|---------------|
| 100332 | 19JUL1936 | 82 | Male | White | 30032 | DROP |
| 100333 | 11MAR1956 | 62 | Male | White | 30033 | DROP |
| 100334 | 01MAY1946 | 72 | Male | White | 30034 | GEL |
| 100335 | 06OCT1938 | 80 | Female | White | 30035 | DROP |
| 100336 | 19SEP1936 | 82 | Female | White | 30036 | GEL |
| 100337 | 02JAN1946 | 72 | Male | White | 30037 | GEL |
| 100338 | 26AUG1931 | 87 | Female | White | 30038 | DROP |
| 100339 | 27JAN1962 | 56 | Male | White | 30039 | GEL |
| 100340 | 05FEB1935 | 83 | Male | White | 30040 | DROP |
| 100341 | 19JUL1930 | 88 | Male | White | 30041 | GEL |
| 100342 | 20JUL1932 | 86 | Female | White | 30042 | DROP |
| 100343 | 18JUL1944 | 74 | Male | White | 30043 | GEL |
| 100344 | 16JAN1950 | 68 | Female | White | 30044 | DROP |
| 100345 | 02JAN1970 | 48 | Male | Black | 30045 | GEL |
| 100346 | 25SEP1941 | 77 | Female | White | 30046 | DROP |
| 100347 | 20OCT1960 | 58 | Male | White | 30047 | GEL |
| 100348 | 08APR1980 | 38 | Female | White | 30048 | GEL |
| 100349 | 07JUL1947 | 71 | Male | White | 30049 | DROP |
| 100350 | 25SEP1951 | 67 | Female | White | 30050 | DROP |
| 100351 | 29APR1939 | 79 | Female | White | 30051 | GEL |
| 100352 | 26JUL1955 | 63 | Female | White | 30052 | DROP |
| 100353 | 19MAR1946 | 72 | Female | White | 30053 | GEL |

Listing 1 (8 of 9): Patient Information/ Registration

| Sbj Code | Date of birth | Age* (yrs) | Sex | If Race=Other, Race specify | Randomiz. Number | Study Drug |
|-------------|------------------|---------------|--------|--------------------------------|---------------------|---------------|
| 100354 | 25JAN1938 | 80 | Female | White | 30054 | GEL |
| 100355 | 04APR1938 | 80 | Female | White | 30055 | DROP |
| 100356 | 16SEP1944 | 74 | Male | White | 30056 | GEL |
| 200101 | 18OCT1952 | 66 | Female | White | 40001 | GEL |
| 200102 | 06AUG1942 | 76 | Female | White | 40002 | DROP |
| 200103 | 18FEB1936 | 82 | Male | White | 40003 | DROP |
| 200104 | 21SEP1940 | 78 | Female | White | 40004 | GEL |
| 200105 | 11JUN1953 | 65 | Female | White | 40005 | GEL |
| 200106 | 04SEP1943 | 75 | Female | White | 40006 | DROP |
| 200107 | 31JULL1964 | 54 | Female | White | 40007 | DROP |
| 200108 | 17OCT1941 | 77 | Male | White | 40008 | GEL |
| 200109 | 14DEC1934 | 84 | Female | White | 40009 | GEL |
| 200110 | 15SEP1954 | 64 | Male | White | 40010 | DROP |
| 200111 | 26APR1945 | 73 | Male | White | 40011 | GEL |
| 200112 | 01JUN1933 | 85 | Male | White | 40012 | DROP |
| 200113 | 12JAN1941 | 77 | Male | White | 40013 | DROP |
| 200114 | 21FEB1954 | 64 | Female | White | 40014 | DROP |
| 200115 | 16JUN1948 | 70 | Female | White | 40015 | GEL |
| 200201 | 30SEP1947 | 71 | Female | White | | |
| 200202 | 05APR1947 | 71 | Female | White | 50001 | DROP |

Listing 1 (9 of 9): Patient Information/ Registration

```
=====
Sbj      Date of          Age*        If Race=Other, Randomiz. Study
Code     birth           Sex      (yrs)      Race   specify       Number    Drug
=====
200203   29APR1952     Male      66        White            50002    GEL
-----
200204   12JAN1960     Male      58        White            50003    GEL
=====
SAS program: L03_List_01.sas - SAS dataset name(s): RAND,DEMOGRAPHY
```

* Age was computed from date of birth and date of informed consent

Listing 2 (1 of 9): Eligibility criteria

Listing 2 (2 of 9): Eligibility criteria

Listing 2 (3 of 9): Eligibility criteria

Listing 2 (4 of 9): Eligibility criteria

Listing 2 (5 of 9): Eligibility criteria

Listing 2 (6 of 9): Eligibility criteria

Listing 2 (7 of 9): Eligibility criteria

Listing 2 (8 of 9): Eligibility criteria

Listing 2 (9 of 9): Eligibility criteria

| Sbj | Study | Age | consent | Informed | | | | | | | | Exclusion criteria | | | | | | | | | | | | | | | | | | | |
|--------|-------|--------|---------|-----------|-----|-----|-----|-----|-----|-----|-----|--------------------|----|----|----|----|----|----|----|----|----|----|----|-----|----|----|----|----|----|----|----|
| | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| Code | drug | Sex | (year) | date | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 200112 | DROP | Male | 85 | 18NOV2018 | Yes | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | |
| 200113 | DROP | Male | 77 | 18NOV2018 | Yes | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | |
| 200114 | DROP | Female | 64 | 12NOV2018 | Yes | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | |
| 200115 | GEL | Female | 70 | 06DEC2018 | Yes | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | |
| 200201 | | Female | 71 | 24JAN2018 | Yes | No | No | No | No | No | No | No | No | No | No | No | No | Yes | No | No | No | NA | No | No | |
| 200202 | DROP | Female | 71 | 13JUN2018 | Yes | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | |
| 200203 | GEL | Male | 66 | 21JUN2018 | Yes | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | NA | NA | No | No | |
| 200204 | GEL | Male | 58 | 28JUN2018 | Yes | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | NA | NA | No | No | |

SAS program: L03_List_02.sas - SAS dataset name(s): RAND,DEMOGRAPHY,INCLUSION,EXCLUSION

Listing 3 (1 of 9): Screening visit - Pregnancy test

| Pregnancy test | | | | | |
|----------------|-------|--------|------------|------------|--------------------------------|
| Sbj | Study | Age | Performed? | Result | |
| Code | drug | Sex | (year) | Visit date | |
| 100101 | DROP | Female | 84 | 20OCT2017 | NA (out of childbearing age) . |
| 100102 | GEL | Male | 80 | 27OCT2017 | NA (male) . |
| 100103 | | Female | 70 | 27OCT2017 | NA (out of childbearing age) . |
| 100104 | GEL | Male | 70 | 03NOV2017 | NA (male) . |
| 100105 | DROP | Female | 85 | 03NOV2017 | NA (out of childbearing age) . |
| 100106 | GEL | Male | 56 | 09NOV2017 | NA (male) . |
| 100107 | DROP | Female | 82 | 23NOV2017 | NA (out of childbearing age) . |
| 100108 | DROP | Female | 73 | 01DEC2017 | NA (out of childbearing age) . |
| 100109 | GEL | Female | 56 | 07DEC2017 | NA (out of childbearing age) . |
| 100110 | DROP | Female | 75 | 07DEC2017 | NA (out of childbearing age) . |
| 100111 | DROP | Female | 60 | 07DEC2017 | NA (out of childbearing age) . |
| 100112 | GEL | Male | 73 | 28DEC2017 | NA (male) . |
| 100113 | GEL | Female | 77 | 28DEC2017 | NA (out of childbearing age) . |
| 100114 | GEL | Male | 64 | 29DEC2017 | NA (male) . |
| 100115 | DROP | Male | 76 | 29DEC2017 | NA (male) . |
| 100116 | GEL | Male | 62 | 29DEC2017 | NA (male) . |
| 100117 | DROP | Female | 51 | 04JAN2018 | NA (out of childbearing age) . |
| 100118 | DROP | Female | 78 | 11JAN2018 | NA (out of childbearing age) . |
| 100119 | DROP | Female | 72 | 19JAN2018 | NA (out of childbearing age) . |
| 100120 | GEL | Male | 79 | 19JAN2018 | NA (male) . |
| 100121 | GEL | Male | 80 | 19JAN2018 | NA (male) . |

Listing 3 (2 of 9): Screening visit - Pregnancy test

| Pregnancy test | | | | | |
|----------------|-------|--------|------------|------------|--------------------------------|
| Sbj | Study | Age | Performed? | Result | |
| Code | drug | Sex | (year) | Visit date | |
| 100122 | DROP | Female | 76 | 19JAN2018 | NA (out of childbearing age) . |
| 100123 | DROP | Female | 76 | 19JAN2018 | NA (out of childbearing age) . |
| 100124 | GEL | Female | 71 | 26JAN2018 | NA (out of childbearing age) . |
| 100125 | GEL | Female | 62 | 26JAN2018 | NA (out of childbearing age) . |
| 100126 | GEL | Female | 85 | 02FEB2018 | NA (out of childbearing age) . |
| 100127 | GEL | Female | 68 | 02FEB2018 | NA (out of childbearing age) . |
| 100128 | DROP | Male | 80 | 02FEB2018 | NA (male) . |
| 100129 | DROP | Female | 78 | 02FEB2018 | NA (out of childbearing age) . |
| 100130 | GEL | Male | 66 | 16FEB2018 | NA (male) . |
| 100131 | DROP | Female | 77 | 16FEB2018 | NA (out of childbearing age) . |
| 100132 | DROP | Male | 69 | 02MAR2018 | NA (male) . |
| 100133 | GEL | Male | 74 | 02MAR2018 | NA (male) . |
| 100134 | DROP | Female | 66 | 02MAR2018 | NA (out of childbearing age) . |
| 100135 | GEL | Male | 69 | 09MAR2018 | NA (male) . |
| 100136 | GEL | Female | 90 | 30MAR2018 | NA (out of childbearing age) . |
| 100137 | DROP | Female | 62 | 13APR2018 | NA (out of childbearing age) . |
| 100138 | GEL | Male | 63 | 13APR2018 | NA (male) . |
| 100139 | DROP | Female | 71 | 20APR2018 | NA (out of childbearing age) . |
| 100140 | GEL | Male | 81 | 27APR2018 | NA (male) . |
| 100141 | DROP | Female | 74 | 27APR2018 | NA (out of childbearing age) . |
| 100142 | GEL | Female | 77 | 11MAY2018 | NA (out of childbearing age) . |

Listing 3 (3 of 9): Screening visit - Pregnancy test

| Pregnancy test | | | | | |
|----------------|-------|--------|------------|------------|------------------------------|
| Sbj | Study | Age | Visit date | Performed? | Result |
| Code | drug | Sex | (year) | | |
| 100143 | GEL | Male | 74 | 15JUN2018 | NA (male) |
| 100144 | DROP | Female | 89 | 22JUN2018 | NA (out of childbearing age) |
| 100145 | GEL | Male | 81 | 29JUN2018 | NA (male) |
| 100146 | GEL | Male | 71 | 17AUG2018 | NA (male) |
| 100147 | DROP | Male | 48 | 24AUG2018 | NA (male) |
| 100148 | DROP | Female | 83 | 24AUG2018 | NA (out of childbearing age) |
| 100149 | DROP | Female | 71 | 24AUG2018 | NA (out of childbearing age) |
| 100150 | GEL | Female | 77 | 31AUG2018 | NA (out of childbearing age) |
| 100151 | DROP | Female | 67 | 28SEP2018 | NA (out of childbearing age) |
| 100152 | GEL | Female | 78 | 28SEP2018 | NA (out of childbearing age) |
| 100153 | DROP | Female | 81 | 12OCT2018 | NA (out of childbearing age) |
| 100154 | GEL | Female | 68 | 12OCT2018 | NA (out of childbearing age) |
| 100155 | DROP | Female | 79 | 12OCT2018 | NA (out of childbearing age) |
| 100156 | GEL | Female | 69 | 12OCT2018 | NA (out of childbearing age) |
| 100201 | GEL | Female | 80 | 01DEC2017 | NA (out of childbearing age) |
| 100202 | DROP | Female | 70 | 01DEC2017 | NA (out of childbearing age) |
| 100203 | DROP | Female | 76 | 07DEC2017 | NA (out of childbearing age) |
| 100204 | GEL | Male | 71 | 07DEC2017 | NA (male) |
| 100205 | GEL | Male | 75 | 14DEC2017 | NA (male) |
| 100206 | DROP | Female | 81 | 05JAN2018 | NA (out of childbearing age) |
| 100207 | DROP | Female | 65 | 05JAN2018 | NA (out of childbearing age) |

Listing 3 (4 of 9): Screening visit - Pregnancy test

| Pregnancy test | | | | | |
|----------------|-------|--------|------------|------------|--------------------------------|
| Sbj | Study | Age | Performed? | Result | |
| Code | drug | Sex | (year) | Visit date | |
| 100208 | GEL | Female | 79 | 05JAN2018 | NA (out of childbearing age) . |
| 100209 | GEL | Female | 77 | 12JAN2018 | NA (out of childbearing age) . |
| 100210 | DROP | Female | 70 | 12JAN2018 | NA (out of childbearing age) . |
| 100211 | GEL | Male | 67 | 12JAN2018 | NA (male) . |
| 100212 | DROP | Female | 82 | 12JAN2018 | NA (out of childbearing age) . |
| 100213 | DROP | Female | 81 | 25JAN2018 | NA (out of childbearing age) . |
| 100214 | DROP | Female | 77 | 05FEB2018 | NA (out of childbearing age) . |
| 100215 | GEL | Female | 83 | 05FEB2018 | NA (out of childbearing age) . |
| 100216 | GEL | Female | 74 | 09FEB2018 | NA (out of childbearing age) . |
| 100217 | DROP | Female | 72 | 02MAR2018 | NA (out of childbearing age) . |
| 100218 | DROP | Male | 72 | 02MAR2018 | NA (male) . |
| 100219 | GEL | Female | 83 | 09MAR2018 | NA (out of childbearing age) . |
| 100220 | GEL | Male | 64 | 09MAR2018 | NA (male) . |
| 100221 | GEL | Female | 76 | 30MAR2018 | NA (out of childbearing age) . |
| 100222 | DROP | Female | 76 | 05APR2018 | NA (out of childbearing age) . |
| 100223 | DROP | Male | 61 | 05APR2018 | NA (male) . |
| 100224 | GEL | Female | 75 | 20APR2018 | NA (out of childbearing age) . |
| 100225 | DROP | Female | 79 | 20APR2018 | NA (out of childbearing age) . |
| 100226 | GEL | Female | 74 | 20APR2018 | NA (out of childbearing age) . |
| 100227 | DROP | Female | 68 | 27APR2018 | NA (out of childbearing age) . |
| 100228 | GEL | Female | 68 | 27APR2018 | NA (out of childbearing age) . |

Listing 3 (5 of 9): Screening visit - Pregnancy test

| Pregnancy test | | | | | |
|----------------|-------|--------|------------|------------|--------------------------------|
| Sbj | Study | Age | Visit date | Performed? | Result |
| Code | drug | Sex | (year) | | |
| 100229 | GEL | Female | 70 | 04MAY2018 | NA (out of childbearing age) . |
| 100230 | GEL | Female | 63 | 04MAY2018 | NA (out of childbearing age) . |
| 100231 | DROP | Female | 74 | 04MAY2018 | NA (out of childbearing age) . |
| 100232 | DROP | Female | 73 | 04MAY2018 | NA (out of childbearing age) . |
| 100233 | GEL | Female | 72 | 18MAY2018 | NA (out of childbearing age) . |
| 100234 | GEL | Female | 73 | 18MAY2018 | NA (out of childbearing age) . |
| 100235 | DROP | Male | 64 | 28MAY2018 | NA (male) . |
| 100236 | DROP | Female | 70 | 28MAY2018 | NA (out of childbearing age) . |
| 100237 | DROP | Male | 73 | 01JUN2018 | NA (male) . |
| 100238 | GEL | Male | 78 | 01JUN2018 | NA (male) . |
| 100239 | DROP | Female | 80 | 08JUN2018 | NA (out of childbearing age) . |
| 100240 | | Female | 72 | 06JUL2018 | NA (out of childbearing age) . |
| 100241 | GEL | Female | 74 | 23OCT2018 | NA (out of childbearing age) . |
| 100242 | GEL | Female | 67 | 31OCT2018 | NA (out of childbearing age) . |
| 100243 | DROP | Male | 74 | 30NOV2018 | NA (male) . |
| 100244 | GEL | Female | 66 | 07DEC2018 | NA (out of childbearing age) . |
| 100245 | DROP | Female | 69 | 07DEC2018 | NA (out of childbearing age) . |
| 100301 | GEL | Female | 68 | 13OCT2017 | NA (out of childbearing age) . |
| 100302 | GEL | Male | 61 | 26OCT2017 | NA (male) . |
| 100303 | DROP | Female | 73 | 26OCT2017 | NA (out of childbearing age) . |
| 100304 | DROP | Male | 58 | 10NOV2017 | NA (male) . |

Listing 3 (6 of 9): Screening visit - Pregnancy test

| Pregnancy test | | | | | |
|----------------|-------|--------|------------|------------|--------------------------------|
| Sbj | Study | Age | Performed? | Result | |
| Code | drug | Sex | (year) | Visit date | |
| 100305 | DROP | Female | 85 | 10NOV2017 | NA (out of childbearing age) . |
| 100306 | DROP | Female | 84 | 16NOV2017 | NA (out of childbearing age) . |
| 100307 | GEL | Female | 73 | 24NOV2017 | NA (out of childbearing age) . |
| 100308 | GEL | Female | 85 | 24NOV2017 | NA (out of childbearing age) . |
| 100309 | DROP | Female | 61 | 24NOV2017 | NA (out of childbearing age) . |
| 100310 | GEL | Female | 73 | 24NOV2017 | NA (out of childbearing age) . |
| 100311 | GEL | Female | 83 | 29NOV2017 | NA (out of childbearing age) . |
| 100312 | DROP | Female | 71 | 29NOV2017 | NA (out of childbearing age) . |
| 100313 | GEL | Male | 71 | 29NOV2017 | NA (male) . |
| 100314 | DROP | Male | 67 | 30NOV2017 | NA (male) . |
| 100315 | GEL | Female | 65 | 30NOV2017 | NA (out of childbearing age) . |
| 100316 | DROP | Male | 76 | 30NOV2017 | NA (male) . |
| 100317 | GEL | Male | 85 | 30NOV2017 | NA (male) . |
| 100318 | GEL | Female | 80 | 30NOV2017 | NA (out of childbearing age) . |
| 100319 | DROP | Male | 70 | 29NOV2017 | NA (male) . |
| 100320 | DROP | Male | 69 | 30NOV2017 | NA (male) . |
| 100321 | GEL | Male | 72 | 06DEC2017 | NA (male) . |
| 100322 | GEL | Male | 80 | 06DEC2017 | NA (male) . |
| 100323 | DROP | Female | 76 | 06DEC2017 | NA (out of childbearing age) . |
| 100324 | DROP | Male | 65 | 13DEC2017 | NA (male) . |
| 100325 | GEL | Female | 83 | 13DEC2017 | NA (out of childbearing age) . |

Listing 3 (7 of 9): Screening visit - Pregnancy test

| Pregnancy test | | | | | |
|----------------|-------|--------|------------|------------|------------------------------|
| Sbj | Study | Age | Visit date | Performed? | Result |
| Code | drug | Sex | (year) | | |
| 100326 | DROP | Male | 81 | 13DEC2017 | NA (male) |
| 100327 | GEL | Female | 73 | 13DEC2017 | NA (out of childbearing age) |
| 100328 | DROP | Male | 82 | 13DEC2017 | NA (male) |
| 100329 | GEL | Male | 74 | 13DEC2017 | NA (male) |
| 100330 | DROP | Male | 61 | 14DEC2017 | NA (male) |
| 100331 | GEL | Female | 71 | 14DEC2017 | NA (out of childbearing age) |
| 100332 | DROP | Male | 82 | 05JAN2018 | NA (male) |
| 100333 | DROP | Male | 62 | 19JAN2018 | NA (male) |
| 100334 | GEL | Male | 72 | 19JAN2018 | NA (male) |
| 100335 | DROP | Female | 80 | 31JAN2018 | NA (out of childbearing age) |
| 100336 | GEL | Female | 82 | 01MAR2018 | NA (out of childbearing age) |
| 100337 | GEL | Male | 72 | 10MAR2018 | NA (male) |
| 100338 | DROP | Female | 87 | 15MAR2018 | NA (out of childbearing age) |
| 100339 | GEL | Male | 56 | 22MAR2018 | NA (out of childbearing age) |
| 100340 | DROP | Male | 83 | 05APR2018 | NA (male) |
| 100341 | GEL | Male | 88 | 05APR2018 | NA (male) |
| 100342 | DROP | Female | 86 | 05APR2018 | NA (out of childbearing age) |
| 100343 | GEL | Male | 74 | 05APR2018 | NA (male) |
| 100344 | DROP | Female | 68 | 05APR2018 | NA (out of childbearing age) |
| 100345 | GEL | Male | 48 | 05APR2018 | NA (male) |
| 100346 | DROP | Female | 77 | 06APR2018 | NA (out of childbearing age) |

Listing 3 (8 of 9): Screening visit - Pregnancy test

| Pregnancy test | | | | | |
|----------------|-------|--------|------------|------------|------------------------------|
| Sbj | Study | Age | Performed? | Result | |
| Code | drug | Sex | (year) | Visit date | |
| 100347 | GEL | Male | 58 | 12APR2018 | NA (male) |
| 100348 | GEL | Female | 38 | 19APR2018 | No |
| 100349 | DROP | Male | 71 | 18MAY2018 | NA (male) |
| 100350 | DROP | Female | 67 | 18MAY2018 | NA (out of childbearing age) |
| 100351 | GEL | Female | 79 | 18MAY2018 | NA (out of childbearing age) |
| 100352 | DROP | Female | 63 | 23MAY2018 | NA (out of childbearing age) |
| 100353 | GEL | Female | 72 | 31MAY2018 | NA (out of childbearing age) |
| 100354 | GEL | Female | 80 | 01JUN2018 | NA (out of childbearing age) |
| 100355 | DROP | Female | 80 | 08JUN2018 | NA (out of childbearing age) |
| 100356 | GEL | Male | 74 | 12JUN2018 | NA (male) |
| 200101 | GEL | Female | 66 | 11JAN2018 | NA (out of childbearing age) |
| 200102 | DROP | Female | 76 | 25JAN2018 | NA (out of childbearing age) |
| 200103 | DROP | Male | 82 | 12FEB2018 | NA (male) |
| 200104 | GEL | Female | 78 | 03MAY2018 | NA (out of childbearing age) |
| 200105 | GEL | Female | 65 | 24MAY2018 | NA (out of childbearing age) |
| 200106 | DROP | Female | 75 | 18JUN2018 | NA (out of childbearing age) |
| 200107 | DROP | Female | 54 | 25JUN2018 | NA (out of childbearing age) |
| 200108 | GEL | Male | 77 | 29AUG2018 | NA (male) |
| 200109 | GEL | Female | 84 | 29SEP2018 | NA (out of childbearing age) |
| 200110 | DROP | Male | 64 | 05OCT2018 | NA (male) |
| 200111 | GEL | Male | 73 | 01NOV2018 | NA (male) |

Listing 3 (9 of 9): Screening visit - Pregnancy test

| Pregnancy test | | | | | |
|----------------|-------|--------|------------|------------|------------------------------|
| Sbj | Study | Age | Performed? | Result | |
| Code | drug | Sex | (year) | Visit date | |
| 200112 | DROP | Male | 85 | 09NOV2018 | NA (male) |
| 200113 | DROP | Male | 77 | 09NOV2018 | NA (male) |
| 200114 | DROP | Female | 64 | 23NOV2018 | NA (out of childbearing age) |
| 200115 | GEL | Female | 70 | 14DEC2018 | NA (out of childbearing age) |
| 200201 | | Female | 71 | 24JAN2018 | . |
| 200202 | DROP | Female | 71 | 13JUN2018 | NA (out of childbearing age) |
| 200203 | GEL | Male | 66 | 21JUN2018 | NA (male) |
| 200204 | GEL | Male | 58 | 28JUN2018 | NA (male) |

SAS program: L03_List_03.sas - SAS dataset name(s): RAND,DEMOGRAPHY,PREGNANCY

Listing 4 (1 of 9): Screening visit - Amsler and OCT tests at study entry

| Sbj | Study | Age | Amsler test | | OCT test | | | |
|--------|-------|--------|-------------|------|----------|----------|------------|----------|
| | | | Code | drug | Sex | (year) | Performed? | Result |
| 100101 | DROP | Female | 84 | Yes | | Negative | Yes | Negative |
| 100102 | GEL | Male | 80 | Yes | | Negative | Yes | Negative |
| 100103 | | Female | 70 | Yes | | Negative | Yes | Negative |
| 100104 | GEL | Male | 70 | Yes | | Negative | Yes | Negative |
| 100105 | DROP | Female | 85 | Yes | | Negative | Yes | Negative |
| 100106 | GEL | Male | 56 | Yes | | Negative | Yes | Negative |
| 100107 | DROP | Female | 82 | Yes | | Negative | Yes | Negative |
| 100108 | DROP | Female | 73 | Yes | | Negative | Yes | Negative |
| 100109 | GEL | Female | 56 | Yes | | Negative | Yes | Negative |
| 100110 | DROP | Female | 75 | Yes | | Negative | Yes | Negative |
| 100111 | DROP | Female | 60 | Yes | | Negative | Yes | Negative |
| 100112 | GEL | Male | 73 | Yes | | Negative | Yes | Negative |
| 100113 | GEL | Female | 77 | Yes | | Negative | Yes | Negative |
| 100114 | GEL | Male | 64 | Yes | | Negative | Yes | Negative |
| 100115 | DROP | Male | 76 | Yes | | Negative | Yes | Negative |
| 100116 | GEL | Male | 62 | Yes | | Negative | Yes | Negative |
| 100117 | DROP | Female | 51 | Yes | | Negative | Yes | Negative |
| 100118 | DROP | Female | 78 | Yes | | Negative | Yes | Negative |
| 100119 | DROP | Female | 72 | Yes | | Negative | Yes | Negative |
| 100120 | GEL | Male | 79 | Yes | | Negative | Yes | Negative |
| 100121 | GEL | Male | 80 | Yes | | Negative | Yes | Negative |

Listing 4 (2 of 9): Screening visit - Amsler and OCT tests at study entry

| Sbj Code | Study drug | Age (year) | Amsler test | | OCT test | |
|-------------|---------------|---------------|-------------|------------|----------|------------|
| | | | Sex | Performed? | Result | Performed? |
| 100122 | DROP | Female 76 | Yes | Negative | Yes | Negative |
| 100123 | DROP | Female 76 | Yes | Negative | Yes | Negative |
| 100124 | GEL | Female 71 | Yes | Negative | Yes | Negative |
| 100125 | GEL | Female 62 | Yes | Negative | Yes | Negative |
| 100126 | GEL | Female 85 | Yes | Negative | Yes | Negative |
| 100127 | GEL | Female 68 | Yes | Negative | Yes | Negative |
| 100128 | DROP | Male 80 | Yes | Negative | Yes | Negative |
| 100129 | DROP | Female 78 | Yes | Negative | Yes | Negative |
| 100130 | GEL | Male 66 | Yes | Negative | Yes | Negative |
| 100131 | DROP | Female 77 | Yes | Negative | Yes | Negative |
| 100132 | DROP | Male 69 | Yes | Negative | Yes | Negative |
| 100133 | GEL | Male 74 | Yes | Negative | Yes | Negative |
| 100134 | DROP | Female 66 | Yes | Negative | Yes | Negative |
| 100135 | GEL | Male 69 | Yes | Negative | Yes | Negative |
| 100136 | GEL | Female 90 | Yes | Negative | Yes | Negative |
| 100137 | DROP | Female 62 | Yes | Negative | Yes | Negative |
| 100138 | GEL | Male 63 | Yes | Negative | Yes | Negative |
| 100139 | DROP | Female 71 | Yes | Negative | Yes | Negative |
| 100140 | GEL | Male 81 | Yes | Negative | Yes | Negative |
| 100141 | DROP | Female 74 | Yes | Negative | Yes | Negative |
| 100142 | GEL | Female 77 | Yes | Negative | Yes | Negative |

Listing 4 (3 of 9): Screening visit - Amsler and OCT tests at study entry

| Sbj Code | Study drug | Age (year) | Amsler test | | OCT test | |
|-------------|---------------|---------------|-------------|------------|----------|------------|
| | | | Sex | Performed? | Result | Performed? |
| 100143 | GEL | Male 74 | Yes | Negative | Yes | Negative |
| 100144 | DROP | Female 89 | Yes | Negative | Yes | Negative |
| 100145 | GEL | Male 81 | Yes | Negative | Yes | Negative |
| 100146 | GEL | Male 71 | Yes | Negative | Yes | Negative |
| 100147 | DROP | Male 48 | Yes | Negative | Yes | Negative |
| 100148 | DROP | Female 83 | Yes | Negative | Yes | Negative |
| 100149 | DROP | Female 71 | Yes | Negative | Yes | Negative |
| 100150 | GEL | Female 77 | Yes | Negative | Yes | Negative |
| 100151 | DROP | Female 67 | Yes | Negative | Yes | Negative |
| 100152 | GEL | Female 78 | Yes | Negative | Yes | Negative |
| 100153 | DROP | Female 81 | Yes | Negative | Yes | Negative |
| 100154 | GEL | Female 68 | Yes | Negative | Yes | Negative |
| 100155 | DROP | Female 79 | Yes | Negative | Yes | Negative |
| 100156 | GEL | Female 69 | Yes | Negative | Yes | Negative |
| 100201 | GEL | Female 80 | Yes | Negative | Yes | Negative |
| 100202 | DROP | Female 70 | Yes | Negative | Yes | Negative |
| 100203 | DROP | Female 76 | Yes | Negative | Yes | Negative |
| 100204 | GEL | Male 71 | Yes | Negative | Yes | Negative |
| 100205 | GEL | Male 75 | Yes | Negative | Yes | Negative |
| 100206 | DROP | Female 81 | Yes | Negative | Yes | Negative |
| 100207 | DROP | Female 65 | Yes | Negative | Yes | Negative |

Listing 4 (4 of 9): Screening visit - Amsler and OCT tests at study entry

| Sbj Code | Study drug | Age (year) | Amsler test | | OCT test | |
|-------------|---------------|---------------|-------------|------------|----------|------------|
| | | | Sex | Performed? | Result | Performed? |
| 100208 | GEL | Female 79 | Yes | Negative | Yes | Negative |
| 100209 | GEL | Female 77 | Yes | Negative | Yes | Negative |
| 100210 | DROP | Female 70 | Yes | Negative | Yes | Negative |
| 100211 | GEL | Male 67 | Yes | Negative | Yes | Negative |
| 100212 | DROP | Female 82 | Yes | Negative | Yes | Negative |
| 100213 | DROP | Female 81 | Yes | Negative | Yes | Negative |
| 100214 | DROP | Female 77 | Yes | Negative | Yes | Negative |
| 100215 | GEL | Female 83 | Yes | Negative | Yes | Negative |
| 100216 | GEL | Female 74 | Yes | Negative | Yes | Negative |
| 100217 | DROP | Female 72 | Yes | Negative | Yes | Negative |
| 100218 | DROP | Male 72 | Yes | Negative | Yes | Negative |
| 100219 | GEL | Female 83 | Yes | Negative | Yes | Negative |
| 100220 | GEL | Male 64 | Yes | Negative | Yes | Negative |
| 100221 | GEL | Female 76 | Yes | Negative | Yes | Negative |
| 100222 | DROP | Female 76 | Yes | Negative | Yes | Negative |
| 100223 | DROP | Male 61 | Yes | Negative | Yes | Negative |
| 100224 | GEL | Female 75 | Yes | Negative | Yes | Negative |
| 100225 | DROP | Female 79 | Yes | Negative | Yes | Negative |
| 100226 | GEL | Female 74 | Yes | Negative | Yes | Negative |
| 100227 | DROP | Female 68 | Yes | Negative | Yes | Negative |
| 100228 | GEL | Female 68 | Yes | Negative | Yes | Negative |

Listing 4 (5 of 9): Screening visit - Amsler and OCT tests at study entry

| Sbj Code | Study drug | Age (year) | Amsler test | | OCT test | |
|-------------|---------------|---------------|-------------|------------|----------|------------|
| | | | Sex | Performed? | Result | Performed? |
| 100229 | GEL | Female 70 | Yes | Negative | Yes | Negative |
| 100230 | GEL | Female 63 | Yes | Negative | Yes | Negative |
| 100231 | DROP | Female 74 | Yes | Negative | Yes | Negative |
| 100232 | DROP | Female 73 | Yes | Negative | Yes | Negative |
| 100233 | GEL | Female 72 | Yes | Negative | Yes | Negative |
| 100234 | GEL | Female 73 | Yes | Negative | Yes | Negative |
| 100235 | DROP | Male 64 | Yes | Negative | Yes | Negative |
| 100236 | DROP | Female 70 | Yes | Negative | Yes | Negative |
| 100237 | DROP | Male 73 | Yes | Negative | Yes | Negative |
| 100238 | GEL | Male 78 | Yes | Negative | Yes | Negative |
| 100239 | DROP | Female 80 | Yes | Negative | Yes | Negative |
| 100240 | | Female 72 | Yes | Negative | Yes | Negative |
| 100241 | GEL | Female 74 | Yes | Negative | Yes | Negative |
| 100242 | GEL | Female 67 | Yes | Negative | Yes | Negative |
| 100243 | DROP | Male 74 | Yes | Negative | Yes | Negative |
| 100244 | GEL | Female 66 | Yes | Negative | Yes | Negative |
| 100245 | DROP | Female 69 | Yes | Negative | Yes | Negative |
| 100301 | GEL | Female 68 | Yes | Negative | Yes | Negative |
| 100302 | GEL | Male 61 | Yes | Negative | Yes | Negative |
| 100303 | DROP | Female 73 | Yes | Negative | Yes | Negative |
| 100304 | DROP | Male 58 | Yes | Negative | Yes | Negative |

Listing 4 (6 of 9): Screening visit - Amsler and OCT tests at study entry

| Sbj | Study | Age | Amsler test | | OCT test | | | |
|--------|-------|--------|-------------|------|----------|----------|------------|----------|
| | | | Code | drug | Sex | (year) | Performed? | Result |
| 100305 | DROP | Female | 85 | Yes | | Negative | Yes | Negative |
| 100306 | DROP | Female | 84 | Yes | | Negative | Yes | Negative |
| 100307 | GEL | Female | 73 | Yes | | Negative | Yes | Negative |
| 100308 | GEL | Female | 85 | Yes | | Negative | Yes | Negative |
| 100309 | DROP | Female | 61 | Yes | | Negative | Yes | Negative |
| 100310 | GEL | Female | 73 | Yes | | Negative | Yes | Negative |
| 100311 | GEL | Female | 83 | Yes | | Negative | Yes | Negative |
| 100312 | DROP | Female | 71 | Yes | | Negative | Yes | Negative |
| 100313 | GEL | Male | 71 | Yes | | Negative | Yes | Negative |
| 100314 | DROP | Male | 67 | Yes | | Negative | Yes | Negative |
| 100315 | GEL | Female | 65 | Yes | | Negative | Yes | Negative |
| 100316 | DROP | Male | 76 | Yes | | Negative | Yes | Negative |
| 100317 | GEL | Male | 85 | Yes | | Negative | Yes | Negative |
| 100318 | GEL | Female | 80 | Yes | | Negative | Yes | Negative |
| 100319 | DROP | Male | 70 | Yes | | Negative | Yes | Negative |
| 100320 | DROP | Male | 69 | Yes | | Negative | Yes | Negative |
| 100321 | GEL | Male | 72 | Yes | | Negative | Yes | Negative |
| 100322 | GEL | Male | 80 | Yes | | Negative | Yes | Negative |
| 100323 | DROP | Female | 76 | Yes | | Negative | Yes | Negative |
| 100324 | DROP | Male | 65 | Yes | | Negative | Yes | Negative |
| 100325 | GEL | Female | 83 | Yes | | Negative | Yes | Negative |

Listing 4 (7 of 9): Screening visit - Amsler and OCT tests at study entry

| Sbj Code | Study drug | Age (year) | Amsler test | | OCT test | |
|-------------|---------------|---------------|-------------|------------|----------|------------|
| | | | Sex | Performed? | Result | Performed? |
| 100326 | DROP | Male 81 | Yes | Negative | Yes | Negative |
| 100327 | GEL | Female 73 | Yes | Negative | Yes | Negative |
| 100328 | DROP | Male 82 | Yes | Negative | Yes | Negative |
| 100329 | GEL | Male 74 | Yes | Negative | Yes | Negative |
| 100330 | DROP | Male 61 | Yes | Negative | Yes | Negative |
| 100331 | GEL | Female 71 | Yes | Negative | Yes | Negative |
| 100332 | DROP | Male 82 | Yes | Negative | Yes | Negative |
| 100333 | DROP | Male 62 | Yes | Negative | Yes | Negative |
| 100334 | GEL | Male 72 | Yes | Negative | Yes | Negative |
| 100335 | DROP | Female 80 | Yes | Negative | Yes | Negative |
| 100336 | GEL | Female 82 | Yes | Negative | Yes | Negative |
| 100337 | GEL | Male 72 | Yes | Negative | Yes | Negative |
| 100338 | DROP | Female 87 | Yes | Negative | Yes | Negative |
| 100339 | GEL | Male 56 | Yes | Negative | Yes | Negative |
| 100340 | DROP | Male 83 | Yes | Negative | Yes | Negative |
| 100341 | GEL | Male 88 | Yes | Negative | Yes | Negative |
| 100342 | DROP | Female 86 | Yes | Negative | Yes | Negative |
| 100343 | GEL | Male 74 | Yes | Negative | Yes | Negative |
| 100344 | DROP | Female 68 | Yes | Negative | Yes | Negative |
| 100345 | GEL | Male 48 | Yes | Negative | Yes | Negative |
| 100346 | DROP | Female 77 | Yes | Negative | Yes | Negative |

Listing 4 (8 of 9): Screening visit - Amsler and OCT tests at study entry

| Sbj Code | Study drug | Age (year) | Amsler test | | OCT test | |
|-------------|---------------|---------------|-------------|------------|----------|------------|
| | | | Sex | Performed? | Result | Performed? |
| 100347 | GEL | Male 58 | Yes | Negative | Yes | Negative |
| 100348 | GEL | Female 38 | Yes | Negative | Yes | Negative |
| 100349 | DROP | Male 71 | Yes | Negative | Yes | Negative |
| 100350 | DROP | Female 67 | Yes | Negative | Yes | Negative |
| 100351 | GEL | Female 79 | Yes | Negative | Yes | Negative |
| 100352 | DROP | Female 63 | Yes | Negative | Yes | Negative |
| 100353 | GEL | Female 72 | Yes | Negative | Yes | Negative |
| 100354 | GEL | Female 80 | Yes | Negative | Yes | Negative |
| 100355 | DROP | Female 80 | Yes | Negative | Yes | Negative |
| 100356 | GEL | Male 74 | Yes | Negative | Yes | Negative |
| 200101 | GEL | Female 66 | Yes | Negative | Yes | Negative |
| 200102 | DROP | Female 76 | Yes | Negative | Yes | Negative |
| 200103 | DROP | Male 82 | Yes | Negative | Yes | Negative |
| 200104 | GEL | Female 78 | Yes | Negative | Yes | Negative |
| 200105 | GEL | Female 65 | Yes | Negative | Yes | Negative |
| 200106 | DROP | Female 75 | Yes | Negative | Yes | Negative |
| 200107 | DROP | Female 54 | Yes | Negative | Yes | Negative |
| 200108 | GEL | Male 77 | Yes | Negative | Yes | Negative |
| 200109 | GEL | Female 84 | Yes | Negative | Yes | Negative |
| 200110 | DROP | Male 64 | Yes | Negative | Yes | Negative |
| 200111 | GEL | Male 73 | Yes | Negative | Yes | Negative |

Listing 4 (9 of 9): Screening visit - Amsler and OCT tests at study entry

| Sbj Code | Study drug | Age (year) | Amsler test | | OCT test | |
|-------------|---------------|---------------|-------------|------------|----------|------------|
| | | | Sex | Performed? | Result | Performed? |
| 200112 | DROP | Male 85 | Yes | Negative | Yes | Negative |
| 200113 | DROP | Male 77 | Yes | Negative | Yes | Negative |
| 200114 | DROP | Female 64 | Yes | Negative | Yes | Negative |
| 200115 | GEL | Female 70 | Yes | Negative | Yes | Negative |
| 200201 | | Female 71 | . | . | . | . |
| 200202 | DROP | Female 71 | Yes | Negative | Yes | Negative |
| 200203 | GEL | Male 66 | Yes | Negative | Yes | Negative |
| 200204 | GEL | Male 58 | Yes | Negative | Yes | Negative |

SAS program: L03_List_04.sas - SAS dataset name(s): RAND,DEMOGRAPHY,AMSLER,OCT

Listing 5 (1 of 10): Screening visit - General and Ophthalmic medical history at study entry

| General medical history | | | | Ophthalmic medical history | | | | |
|-------------------------|---------------|-------------------|--|----------------------------|------------|---------------|----------------------|---------|
| Sbj Code | Study drug | Age Sex (year) | Reported term | Date of diagnosis | Ongoing | Reported term | Date of diagnosis | Ongoing |
| 100101 | DROP | Female 84 | INTRACAVEROUS MENINGIOMA IPERTENSION | 6MAR1976 4FEB2003 | NO YES | | | |
| 100105 | DROP | Female 85 | IPERTENSION | 8FEB2002 | YES | | | |
| 100106 | GEL | Male 56 | ARTERIAL HYPERTENSION THYROIDECTOMY | 2APR2012 5MAY2004 | YES NO | | | |
| 100110 | DROP | Female 75 | ARTERIAL HYPERTENSION | FEB2007 | YES | | | |
| 100112 | GEL | Male 73 | APPENDICECTOMY ARTERIAL HYPERTENSION | 7FEB1999 20APR2005 | NO YES | | | |
| 100113 | GEL | Female 77 | ARTERIAL HYPERTENSION | 7OCT2013 | YES | | | |
| 100114 | GEL | Male 64 | ARTERIAL HYPERTENSION | 2MAY2012 | YES | | | |
| 100115 | DROP | Male 76 | PRIOR MIOCARDIAL ISCHEMIA | SEP2013 | NO | | | |
| 100118 | DROP | Female 78 | ARTERIAL HYPERTENSION HYPERCHOLESTEROLEMIA | 6OCT2007 23JAN2001 | YES YES | | | |
| 100119 | DROP | Female 72 | ARTERIAL HYPERTENSION | 2002 | YES | | | |
| 100120 | GEL | Male 79 | ARTERIAL HYPERTENSION RENAL CARCINOMA ASPORTATION | 6MAY2005 2011 | YES NO | | | |
| 100121 | GEL | Male 80 | ARTERIAL HYPERTENSION | 2000 | YES | | | |
| 100124 | GEL | Female 71 | ARTERIAL HYPERTENSION | FEB2001 | YES | | | |
| 100126 | GEL | Female 85 | ARTERIAL HYPERTENSION HYPERCHOLESTEROLEMIA | 2005 2008 | YES YES | | | |
| 100128 | DROP | Male 80 | ARTERIAL HYPERTENSION | APR2001 | YES | | | |
| 100130 | GEL | Male 66 | ARTERIAL HYPERTENSION MIOCARDIAL ISCHEMIA | 2000 2017 | YES NO | | | |
| 100131 | DROP | Female 77 | ARTERIAL HYPERTENSION | 2010 | YES | | | |
| 100133 | GEL | Male 74 | ARTERIAL HYPERTENSION | MAR2005 | YES | | | |

Listing 5 (2 of 10): Screening visit - General and Ophthalmic medical history at study entry

| Sbj Code | Study drug | Age (year) | General medical history | | | Ophthalmic medical history | | |
|-------------|---------------|---------------|--------------------------------|----------------------|---------|--------------------------------|----------------------|---------|
| | | | Reported term | Date of diagnosis | Ongoing | Reported term | Date of diagnosis | Ongoing |
| 100145 | GEL | Male 81 | ARTERIAL HYPERTENSION | 2003 | YES | | | |
| . | . | | HYPERCOLESTEROLEMIA | 2003 | YES | | | |
| 100149 | DROP | Female 71 | HYPOTHYROIDISM | 1995 | YES | | | |
| 100153 | DROP | Female 81 | HYPERTENSION | 2003 | YES | | | |
| . | . | | HYPOTHYROIDISM | 2010 | YES | | | |
| 100154 | GEL | Female 68 | ARTERIAL HYPERTHENSION | FEB2007 | YES | | | |
| 100155 | DROP | Female 79 | ARTERIAL HYPERTHENSION | 2002 | YES | | | |
| 100201 | GEL | Female 80 | APPENDICECTOMY | 1957 | NO | LEFT EYE CATARACT SURGERY | 26JAN2017 | NO |
| . | . | | HYSTEROANNESECTOMY | 1990 | NO | RIGHT EYE CATARACT | 2015 | YES |
| . | . | | MENOPAUSE | 1990 | YES | | | |
| . | . | | SYSTEMIC ARTERIAL HYPERTENSION | 2007 | YES | | | |
| 100202 | DROP | Female 70 | LEFT ROTATOR SCUFF SURGERY | SEP2017 | NO | LEFT EYE CATARACT | 2016 | YES |
| . | . | | | | | RIGHT EYE CATARACT | 2016 | YES |
| 100203 | DROP | Female 76 | GASTROESOPHAGEAL REFLUX | 2012 | YES | LEFT EYE CATARACT SURGERY | 2013 | NO |
| . | . | | HYPERCOLESTEROLEMIA | 2007 | YES | LEFT EYE YAG LASER CAPSULOTOMY | 2015 | NO |
| . | . | | HYPERURICEMIA | 2007 | YES | RIGHT EYE CATARACT | 2015 | YES |
| . | . | | INSOMNIA | 2007 | YES | | | |
| . | . | | SYSTEMIC ARTERIAL HYPERTENSION | 2007 | YES | | | |
| 100204 | GEL | Male 71 | ATRIAL FIBRILLATION | 2012 | YES | RIGHT EYE CATARACT | 2016 | YES |
| . | . | | SYSTEMIC ARTERIAL HYPERTENSION | 2012 | YES | | | |
| 100205 | GEL | Male 75 | GASTROESOPHAGEAL REFLUX | 2007 | YES | LEFT EYE CATARACT | 2016 | YES |
| . | . | | SYSTEMIC ARTERIAL HYPERTENSION | 2011 | YES | RIGHT EYE CATARACT | 2016 | YES |
| 100206 | DROP | Female 81 | GASTROESOPHAGEAL REFLUX | 2013 | YES | DRY EYE SYNDROME | 2016 | YES |
| . | . | | HYPERCHOLESTEROLEMIA | 2008 | YES | LEFT EYE CATARACT SURGERY | 19OCT2017 | NO |
| . | . | | | | | RIGHT EYE CATARACT | 2016 | YES |
| 100207 | DROP | Female 65 | HYPERCHOLESTEROLEMIA | 2008 | YES | HIGH MYOPIA | 1967 | YES |
| . | . | | SYSTEMIC ARTERIAL HYPERTENSION | 2013 | YES | LEFT EYE CATARACT | 2015 | YES |
| . | . | | | | | RIGHT EYE CATARACT | 2015 | YES |
| 100208 | GEL | Female 79 | DEPRESSION | 2015 | YES | LEFT EYE CATARACT SURGERY | JAN2016 | NO |

Listing 5 (3 of 10): Screening visit - General and Ophthalmic medical history at study entry

| General medical history | | | | | | | | Ophthalmic medical history | | |
|-------------------------|-------|--------|--------|--------------------------------|---------|---------------|--------------------------------|----------------------------|---------|--|
| Sbj | Study | Age | | Date of diagnosis | Ongoing | Reported term | | Date of diagnosis | Ongoing | |
| Code | drug | Sex | (year) | Reported term | | | | | | |
| 100209 | GEL | Female | 77 | CARDIAC ARRHYTHMIA | 2008 | YES | LEFT EYE CATARACT | 2016 | YES | |
| . | . | . | | INSOMNIA | 2008 | YES | RIGHT EYE CATARACT | 2016 | YES | |
| 100210 | DROP | Female | 70 | HYPERCHOLESTEROLEMIA | 2012 | YES | LEFT EYE CATARACT SURGERY | 12OCT2017 | NO | |
| . | . | . | | | | | RIGHT EYE CATARACT | 2016 | YES | |
| 100211 | GEL | Male | 67 | HYPERCHOLESTEROLEMIA | 2014 | YES | LEFT EYE CATARACT | 2016 | YES | |
| . | . | . | | | | | RIGHT EYE CATARACT | 2016 | YES | |
| 100212 | DROP | Female | 82 | GASTROESOPHAGEAL REFLUX | 2013 | YES | LEFT EYE CATARACT SURGERY | 2016 | YES | |
| . | . | . | | | | | RIGHT EYE CATARACT SURGERY | SEP2017 | YES | |
| 100213 | DROP | Female | 81 | HYPOTHYROIDISM | 1988 | YES | DRY EYE SYNDROME | 2008 | YES | |
| . | . | . | | SYSTEMIC ARTERIAL HYPERTENSION | 1998 | YES | LEFT EYE CATARACT | 2016 | YES | |
| . | . | . | | | | | RIGHT EYE CATARACT SURGERY | 9FEB2017 | YES | |
| 100214 | DROP | Female | 77 | HYPERCHOLESTEROLEMIA | 2000 | YES | LEFT EYE CATARACT | 2016 | YES | |
| . | . | . | | SYSTEMIC ARTERIAL HYPERTENSION | 1996 | YES | RIGHT EYE-VITREORETINAL INTERF | 2017 | YES | |
| | | | | | | | ACE SYNDROME | | | |
| 100215 | GEL | Female | 83 | | | | LEFT EYE CATARACT | 2007 | YES | |
| 100216 | GEL | Female | 74 | | | | LEFT EYE CATARACT | | YES | |
| . | . | . | | | | | RIGHT EYE CATARACT SURGERY | APR2016 | NO | |
| 100217 | DROP | Female | 72 | HYMENOPTERA VENOM ALLERGY | 1978 | YES | LEFT EYE CATARACT SURGERY | 2NOV2017 | NO | |
| . | . | . | | SYSTEMIC ARTERIAL HYPERTENSION | 2008 | YES | RIGHT EYE CATARACT | 2016 | YES | |
| 100218 | DROP | Male | 72 | PROSTATECTOMY | 2014 | NO | LEFT EYE CATARACT SURGERY | 23NOV2017 | NO | |
| . | . | . | | PROSTATIC CANCER | 2014 | NO | | | | |
| 100219 | GEL | Female | 83 | SYSTEMIC ARTERIAL HYPERTENSION | 2013 | YES | CHOROIDAL NEVUS LEFT EYE | JAN2018 | YES | |
| 100220 | GEL | Male | 64 | PULMONARY HYPERTENSION | 2015 | YES | RIGHT EYE CATARACT SURGERY | 14DEC2017 | NO | |
| . | . | . | | SCLERODERMA | 2010 | YES | | | | |
| . | . | . | | SYSTEMIC ARTERIAL HYPERTENSION | 2014 | YES | | | | |
| 100221 | GEL | Female | 76 | SYSTEMIC ARTERIAL HYPERTENSION | 2008 | YES | | | | |
| 100222 | DROP | Female | 76 | SYSTEMIC ARTERIAL HYPERTENSION | 2008 | YES | RIGHT EYE CATARACT SURGERY | 2016 | NO | |
| 100223 | DROP | Male | 61 | ISCHEMIC STROKE | 2015 | NO | | | | |

Listing 5 (4 of 10): Screening visit - General and Ophthalmic medical history at study entry

| Sbj Code | Study drug | Age (year) | General medical history | | Ophthalmic medical history | | |
|-------------|---------------|---------------|--------------------------------|----------------------|----------------------------|--------------------------------|----------------------|
| | | | Reported term | Date of diagnosis | Ongoing | Reported term | Date of diagnosis |
| 100224 | GEL | Female 75 | ANXIETY | 2015 | YES | | |
| . | . | . | CAROTID ENDARTERECTOMY | 2013 | NO | | |
| . | . | . | HYPERLIPIDEMIA | 2013 | YES | | |
| . | . | . | SYSTEMIC ARTERIAL HYPERTENSION | 2005 | YES | | |
| 100225 | DROP | Female 79 | SYSTEMIC HYPERTENSION | 2008 | YES | | |
| 100226 | GEL | Female 74 | DEPRESSION | 2010 | YES | | |
| . | . | . | SYSTEMIC HYPERTENSION | 2008 | YES | | |
| 100227 | DROP | Female 68 | HYPERCHOLESTEROLEMIA | 2012 | YES | | |
| . | . | . | SYSTEMIC HYPERTENSION | 2009 | YES | | |
| 100228 | GEL | Female 68 | HYPERCHOLESTEROLEMIA | 2012 | YES | LEFT EYE CATARACT SURGERY | 2016 NO |
| . | . | . | OSTEOPOROSIS | 2008 | YES | | |
| 100229 | GEL | Female 70 | SYSTEMIC HYPERTENSION | 2011 | YES | | |
| 100231 | DROP | Female 74 | ANXIETY | 2016 | YES | | |
| . | . | . | GASTRO ESOPHAGEAL REFLUX | 2013 | YES | | |
| . | . | . | PIRETARIA ALLERGY | 1964 | YES | | |
| . | . | . | SYSTEMIC HYPERTENSION | 2011 | YES | | |
| 100232 | DROP | Female 73 | MACROLIDES ALLERGY | 1978 | YES | | |
| . | . | . | SYSTEMIC HYPERTENSION | 2010 | YES | | |
| 100233 | GEL | Female 72 | GALLSTONES | 2010 | YES | RIGHT EYE CATARACT SURGERY | 2017 NO |
| . | . | . | HYNOSOMIA | 2015 | YES | | |
| . | . | . | HYPOTHYROIDISM | 2013 | YES | | |
| . | . | . | OSTHEOPOROSIS | 2008 | YES | | |
| . | . | . | SYSTEMIC ARTERIAL HYPERTENSION | 2010 | YES | | |
| 100234 | GEL | Female 73 | ATRIAL FIBRILLATION | 2013 | YES | LEFT EYE CATARACT SURGERY | 2017 NO |
| . | . | . | HYPERCHOLESTEROLEMIA | 2013 | YES | | |
| . | . | . | HYPOTHYROIDISM | 2013 | YES | | |
| . | . | . | SYSTEMIC ARTERIAL HYPERTENSION | 2010 | YES | | |
| 100235 | DROP | Male 64 | | | LEFT EYE CATARACT SURGERY | 2010 | NO |
| 100236 | DROP | Female 70 | OSTEOPOROSIS | 2017 | YES | LEFT EYE RETINAL LASER BARRAGE | 2016 NO |
| 100237 | DROP | Male 73 | PROSTATECTOMY | 2014 | NO | STRABISMUS SURGERY | 1990 NO |

Listing 5 (5 of 10): Screening visit - General and Ophthalmic medical history at study entry

| General medical history | | | | | | | | Ophthalmic medical history | | |
|-------------------------|-------|--------|--------|---|---------|--------------------|----------------------------|----------------------------|---------|--|
| Sbj | Study | Age | | Date of | Ongoing | Reported term | | Date of | Ongoing | |
| Code | drug | Sex | (year) | Reported term | | | | diagnosis | | |
| 100238 | GEL | Male | 78 | CHRONIC HEART FAILURE | 2015 | YES | LEFT EYE CATARACT SURGERY | 2014 | NO | |
| 100239 | DROP | Female | 80 | ATRIAL FIBRILLATION | 2014 | YES | | | | |
| 100240 | | Female | 72 | ASPIRIN, PENICILLIN, ROCEFIRN, SUL PHAMIDIC ACID ALLERGY | 1988 | YES | RIGHT EYE CATARACT SURGERY | 2017 | NO | |
| . | . | . | . | ASTHMA | 2013 | YES | | | | |
| . | . | . | . | HYPERCHOLESTEROLEMIA | 2008 | YES | | | | |
| . | . | . | . | ISCHEMIC CARDIOMYOPATHY | 2012 | YES | | | | |
| 100241 | GEL | Female | 74 | HYPERCOLESTEROLEMIA | 1988 | YES | | | | |
| . | . | . | . | OSTEOPOROSIS | 1988 | YES | | | | |
| 100242 | GEL | Female | 67 | | | CATARACT-BOTH EYES | | 2017 | YES | |
| 100243 | DROP | Male | 74 | ALLERGY TO WASP STINGS | 1998 | YES | CATARACT-BOTH EYES | 2017 | YES | |
| . | . | . | . | HYPERCOLESTEROLEMIA | 2015 | YES | | | | |
| . | . | . | . | ISCHEMIC CARDIOPATHY | 2015 | YES | | | | |
| . | . | . | . | PSORIASIC ARTHRITIS | 2013 | YES | | | | |
| . | . | . | . | SYSTEMIC ARTERIAL HYPERTENSION | 2008 | YES | | | | |
| 100244 | GEL | Female | 66 | ANXIOUS SYNDROME | 2015 | YES | LEFT EYE CATARACT SURGERY | JAN2018 | NO | |
| . | . | . | . | EXTRASYSTOLIA | 2016 | YES | | | | |
| . | . | . | . | PENICILLIN ALLERGY | 1982 | YES | | | | |
| . | . | . | . | SUPERFICIAL THROMBOPHLEBITIS | SEP2018 | YES | | | | |
| 100245 | DROP | Female | 69 | HYDRIC RETENTION | 2017 | YES | CATARACT-BOTH EYES | 2017 | YES | |
| . | . | . | . | HYPERURICEMIA | 2016 | YES | | | | |
| . | . | . | . | WHEAT ALLERGY | 1988 | YES | | | | |
| 100301 | GEL | Female | 68 | ANXIOUS SYNDROME | 2017 | YES | | | | |
| . | . | . | . | OSTEOPENIA | 2015 | YES | | | | |
| 100302 | GEL | Male | 61 | CARDIOVASCULAR DISEASE | UNK | YES | | | | |
| . | . | . | . | DIABETES MELLITUS | UNK | YES | | | | |
| . | . | . | . | DYSLIPIDEMIA | UNK | YES | | | | |
| . | . | . | . | HYPERTENSION | UNK | YES | | | | |
| . | . | . | . | NEFROPATHY | UNK | YES | | | | |
| . | . | . | . | RENAL HYPERPALSIA | UNK | YES | | | | |

Listing 5 (6 of 10): Screening visit - General and Ophthalmic medical history at study entry

| General medical history | | | | Ophthalmic medical history | | | | |
|-------------------------|---------------|------------------------|-----------------------|----------------------------|---------|------------------------|----------------------|---------|
| Sbj | Study Code | Age drug Sex (year) | Reported term | Date of diagnosis | Ongoing | Reported term | Date of diagnosis | Ongoing |
| 100303 | DROP | Female 73 | DIVERTICULOSIS | UNK | YES | | | |
| . | . | . | HYPERTENSION | UNK | YES | | | |
| . | . | . | OSTEOPOROSIS | UNK | YES | | | |
| . | . | . | POLYARTHRROSIS | UNK | YES | | | |
| 100305 | DROP | Female 85 | BRADICARDIA | UNK | YES | PREVIOUS INFARCTION OD | 2016 | NO |
| . | . | . | HYPERTENSION | UNK | YES | | | |
| . | . | . | IPOTIROIDISMO | UNK | YES | | | |
| . | . | . | NEUROPATHY | UNK | NO | | | |
| 100306 | DROP | Female 84 | DEPRESSIVE ANXIETY | UNK | NO | | | |
| . | . | . | DYSLIPIDEMIA | UNK | YES | | | |
| . | . | . | HYPERTENSION | UNK | YES | | | |
| 100307 | GEL | Female 73 | HYPOTHYROIDIM | UNK | YES | | | |
| 100308 | GEL | Female 85 | HYPERCOLESTEROLEMIA | UNK | YES | | | |
| . | . | . | HYPERTENSION | UNK | YES | | | |
| 100309 | DROP | Female 61 | THYROID NODULE | UNK | YES | | | |
| 100310 | GEL | Female 73 | QUADRANTECTOMY | 2009 | NO | | | |
| 100311 | GEL | Female 83 | ANXIOUS SYNDROME | UNK | YES | | | |
| . | . | . | IPOACUSY | UNK | YES | | | |
| . | . | . | SYSTEMIC HIPERTENSION | UNK | YES | | | |
| 100312 | DROP | Female 71 | HYPOTHYROIDIM | UNK | YES | | | |
| . | . | . | SYSTEMIC HIPERTENSION | UNK | YES | | | |
| 100314 | DROP | Male 67 | APPENDICECTOMY | UNK | NO | | | |
| . | . | . | PROSTATIC HYPERTROPHY | UNK | YES | | | |
| 100315 | GEL | Female 65 | ANXIOUS SYNDROME | UNK | YES | | | |
| 100316 | DROP | Male 76 | ANGIOPLASTIC | 2013 | NO | | | |
| . | . | . | PROSTATIC HYPERTROPHY | UNK | YES | | | |
| 100317 | GEL | Male 85 | PROSTATIC HYPERTROPHY | UNK | YES | | | |
| . | . | . | SYSTEMIC HYPERTENSION | UNK | YES | | | |
| 100318 | GEL | Female 80 | SYSTEMIC HYPERTENSION | UNK | YES | | | |

Listing 5 (7 of 10): Screening visit - General and Ophthalmic medical history at study entry

| General medical history | | | | Ophthalmic medical history | | | | |
|-------------------------|---------------|-------------------|-------------------------|----------------------------|---------|---------------|----------------------|---------|
| Sbj Code | Study drug | Age Sex (year) | Reported term | Date of diagnosis | Ongoing | Reported term | Date of diagnosis | Ongoing |
| 100320 | DROP | Male 69 | CARDIOPATHY | UNK | YES | | | |
| . | . | . | DYSLIPIDEMIA | UNK | YES | | | |
| . | . | . | HYPERTENSION | UNK | YES | | | |
| 100321 | GEL | Male 72 | ARTERIAL HYPERTENSION | UNK | YES | | | |
| . | . | . | DIVERTICULOSIS COLON | UNK | YES | | | |
| . | . | . | HYPOTHYROIDISM | UNK | YES | | | |
| . | . | . | PROSTECTOMY | UNK | NO | | | |
| 100322 | GEL | Male 80 | ADENOIDECTOMIA | UNK | NO | | | |
| . | . | . | HYPERTENSION | UNK | YES | | | |
| . | . | . | TONSILLECTOMY | UNK | NO | | | |
| 100323 | DROP | Female 76 | GASTROESOPHAGEAL REFLUX | UNK | YES | | | |
| . | . | . | HYPERCOLESTEROLEMIA | UNK | YES | | | |
| . | . | . | HYSTERECTOMY | UNK | NO | | | |
| . | . | . | MONOCLONAL GAMMAPATHY | UNK | YES | | | |
| . | . | . | NEPHRECTOMY | UNK | NO | | | |
| . | . | . | SYSTEMIC HIPERTENSION | UNK | YES | | | |
| 100324 | DROP | Male 65 | HIATAL HERNIA | UNK | NO | | | |
| 100325 | GEL | Female 83 | SISTEMIC HYPERTENSION | UNK | YES | | | |
| 100326 | DROP | Male 81 | CARDIOPATHY | UNK | YES | | | |
| . | . | . | COLICISTECTOMY | UNK | NO | | | |
| . | . | . | ERNIOPLASTICA | UNK | NO | | | |
| . | . | . | HYPERTENSION | UNK | YES | | | |
| . | . | . | PROSTATIC ADENOMA | UNK | NO | | | |
| . | . | . | THROMBOPHLEBITIS | UNK | NO | | | |
| 100327 | GEL | Female 73 | OSTEOPOROSIS | UNK | YES | | | |
| . | . | . | QUADRANTECTOMY | UNK | NO | | | |
| 100328 | DROP | Male 82 | HYPERCHOLESTEROLEMIA | UNK | YES | | | |
| . | . | . | SYSTEMIC HIPERTENSION | UNK | YES | | | |
| 100329 | GEL | Male 74 | SYSTEMIC HIPERTENSION | UNK | YES | | | |
| . | . | . | VASCULOPHTATY | UNK | YES | | | |
| 100330 | DROP | Male 61 | CARDIOPATHY | UNK | YES | | | |

Listing 5 (8 of 10): Screening visit - General and Ophthalmic medical history at study entry

| General medical history | | | | Ophthalmic medical history | | | | |
|-------------------------|---------------|------------------------|-----------------------|----------------------------|---------|----------------|----------------------|---------|
| Sbj | Study Code | Age drug Sex (year) | Reported term | Date of diagnosis | Ongoing | Reported term | Date of diagnosis | Ongoing |
| 100331 | GEL | Female 71 | CARDIOPATHY | UNK | YES | | | |
| . | . | . | K COLON | 1992 | NO | | | |
| . | . | . | K LUNG | 1994 | NO | | | |
| 100332 | DROP | Male 82 | GASTRITIS | UNK | YES | | | |
| . | . | . | HYPERTENSION | UNK | YES | | | |
| . | . | . | MELANOMA | UNK | YES | | | |
| . | . | . | VASCULOPATHY | UNK | YES | | | |
| 100333 | DROP | Male 62 | INSOMNIA | UNK | YES | | | |
| 100334 | GEL | Male 72 | SYSTEMIC HYPERTENSION | UNK | YES | | | |
| 100335 | DROP | Female 80 | DYSLIPIDEMIA | UNK | YES | | | |
| . | . | . | OSTEOPOROSIS | UNK | YES | | | |
| . | . | . | SYSTEMIC HYPERTENSION | UNK | YES | | | |
| 100336 | GEL | Female 82 | HYPERCOLESTEROLEMY | UNK | YES | | | |
| . | . | . | HYPERTENSION | UNK | YES | | | |
| 100340 | DROP | Male 83 | HYPERTENSION | UNK | YES | | | |
| 100341 | GEL | Male 88 | HYPERTENSION | UNK | YES | | | |
| 100342 | DROP | Female 86 | HYPERTENSION | UNK | YES | | | |
| 100343 | GEL | Male 74 | HYPERCOLESTEROLEMY | UNK | YES | | | |
| . | . | . | HYPERTENSION | UNK | YES | | | |
| 100344 | DROP | Female 68 | HYPERTENSION | UNK | YES | | | |
| 100346 | DROP | Female 77 | HYPERTENSION | UNK | YES | | | |
| . | . | . | HYPOTIROIDISM | UNK | YES | | | |
| 100348 | GEL | Female 38 | | | | MILD AMBLYOPIA | | YES |
| 100350 | DROP | Female 67 | HYPERTENSION | UNK | YES | | | |
| 100351 | GEL | Female 79 | HYPERTENSION | UNK | YES | | | |
| 100353 | GEL | Female 72 | HYPERCOLESTEROLEMY | UNK | YES | | | |

Listing 5 (9 of 10): Screening visit - General and Ophthalmic medical history at study entry

| General medical history | | | | Ophthalmic medical history | | | | |
|-------------------------|---------------|-------------------|---------------------------|----------------------------|---------|---------------|----------------------|---------|
| Sbj Code | Study drug | Age Sex (year) | Reported term | Date of diagnosis | Ongoing | Reported term | Date of diagnosis | Ongoing |
| 100354 | GEL | Female 80 | HYPERTENSION | UNK | YES | | | |
| 100355 | DROP | Female 80 | HYPERCOLESTEROLEMY | UNK | YES | | | |
| 100356 | GEL | Male 74 | HYPERCOLESTEROLEMY | UNK | YES | | | |
| . | . | | HYPERTENSION | UNK | YES | | | |
| 200102 | DROP | Female 76 | HYPERTENSION | UNK | YES | | | |
| 200103 | DROP | Male 82 | ENLARGED PROSTATE | UNK | YES | | | |
| . | . | | HYPERTENSION | UNK | YES | | | |
| 200104 | GEL | Female 78 | LABYRINTHINE VERTIGO | 1992 | YES | | | |
| . | . | | OSTEOPOROSIS | 2015 | YES | | | |
| 200105 | GEL | Female 65 | DIABETIS | 2014 | YES | | | |
| . | . | | HYPERCHOLESTERIE | 2010 | YES | | | |
| . | . | | HYPERTENSION | 2010 | YES | | | |
| 200106 | DROP | Female 75 | DIABETIS | UNK | YES | | | |
| . | . | | HYPERTENSION | UNK | YES | | | |
| . | . | | HYPOTHYROIDISM | UNK | YES | | | |
| . | . | | VITAMIN B12 DEFICIENCY | UNK | YES | | | |
| 200107 | DROP | Female 54 | ASTHMA | UNK | YES | | | |
| . | . | | DIABETIS | UNK | YES | | | |
| . | . | | HYPERTENSION | UNK | YES | | | |
| . | . | | OSTEOPOROSIS | UNK | YES | | | |
| . | . | | SYSTEMIC MASTOCYTOSIS | UNK | YES | | | |
| 200108 | GEL | Male 77 | ELEVATED URIC ACID LEVEL | UNK | YES | | | |
| . | . | | HIGH BLOODPRESSURE | 2008 | YES | | | |
| . | . | | HYPOTHYROIDISM | UNK | YES | | | |
| 200109 | GEL | Female 84 | CONSTIPATION | UNK | YES | | | |
| . | . | | HEART RHYTHM DISTURBANCES | 1990 | YES | | | |
| . | . | | HIGH BLOODPRESSURE | 2008 | YES | | | |
| . | . | | OSTEOPOROSIS | 1998 | YES | | | |
| 200110 | DROP | Male 64 | COPD | UNK | YES | | | |
| . | . | | HIGH BLODDPRESSURE | UNK | YES | | | |

Listing 5 (10 of 10): Screening visit - General and Ophthalmic medical history at study entry

| General medical history | | | | | Ophthalmic medical history | | | |
|-------------------------|---------------|-------------------|---------------------------|----------------------|----------------------------|---|-------------------------------------|----------------|
| Sbj Code | Study drug | Age Sex (year) | Reported term | Date of diagnosis | Ongoing | Reported term | Date of diagnosis | Ongoing |
| 200111 | GEL | Male 73 | BLADDER DISCOMFORT | UNK | YES | | | |
| . | . | . | BORELLIOSIS | UNK | YES | | | |
| . | . | . | GOOUT | UNK | YES | | | |
| . | . | . | HIGH BLOODPRESSURE | UNK | YES | | | |
| . | . | . | POLYNEUROPATHY | UNK | YES | | | |
| . | . | . | STOMACH PAIN | UNK | YES | | | |
| 200112 | DROP | Male 85 | HIGH BLOODPRESSURE | 2006 | YES | | | |
| 200113 | DROP | Male 77 | CIRCULATORY DISORDER | 2013 | YES | | | |
| . | . | . | DEPRESSION | 2017 | YES | | | |
| . | . | . | HIGH CHOLESTEROL | UNK | YES | | | |
| 200114 | DROP | Female 64 | ARTERIAL HYPERTENSION | UNK | YES | | | |
| . | . | . | DIABETIS MELLITUS | UNK | YES | | | |
| . | . | . | GOOUT | UNK | YES | | | |
| . | . | . | HIGH BLOOD PRESSURE | UNK | YES | | | |
| 200115 | GEL | Female 70 | CRONIC PAIN SYDROME | 2017 | YES | | | |
| . | . | . | REFLUX ESOPHAGITIS | 2012 | YES | | | |
| 200202 | DROP | Female 71 | THYROIDITIS | 2004 | YES | | | |
| 200203 | GEL | Male 66 | ARTERIAL HYPERTENSION | JUN2013 | YES | OD: CATARACT OD: RHEGMATOGENOUS RETINAL DETACHMENT OS: RHEGMATOGENOUS PERIPHERAL RETINAL DETACHMENT | 10MAR2014 10MAR2014 25AUG2016 | NO NO NO |
| 200204 | GEL | Male 58 | ARTERIAL HYPERTENSION | 2008 | YES | | | |
| . | . | . | GOOUT | 2008 | YES | | | |
| . | . | . | HYPERURICEMIA | 2008 | YES | | | |
| . | . | . | INGUINAL HERNIA | 1999 | NO | | | |
| . | . | . | TRANSIENT ISCHEMIC ATTACK | 2003 | NO | | | |

SAS program: L03_List_05.sas - SAS dataset(s): RAND,DEMOGRAPHY,MEDHIS_COD,OPHHIS_COD

Listing 6 (1 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|-------------------|--------------|---------------|-----------|--------------|-------|-----------------------|-------|----------|-----------|--|-------------------|------------------|
| | | | | Left eye | Right eye | Operated eye | | Eye | Value | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** |
| | | | | | | Eye | Value | | | | | | | |
| 100101 | DROP | Female 84 | 1 | 20OCT2017 | 0.8 | 0.4 | . | . | . | 13 | 18 | Yes | 0 grade | None |
| . | . | . | 2 | 25OCT2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 26OCT2017 | . | . | Left | 1 | 12 | 12 | . | Yes | 0 grade | None |
| . | . | . | 4 | 02NOV2017 | . | . | Left | . | 18 | 15 | . | Yes | 0 grade | None |
| . | . | . | 5 | 08NOV2017 | . | . | Left | 1 | 17 | 15 | . | Yes | 0 grade | None |
| . | . | . | 6 | 27DEC2017 | . | . | Left | 1 | 16 | 14 | . | Yes | 0 grade | None |
| 100102 | GEL | Male 80 | 1 | 27OCT2017 | 0.6 | 0.6 | . | . | . | 12 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 31OCT2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 01NOV2017 | . | . | Right | 1 | 18 | 12 | . | Yes | 0 grade | None |
| . | . | . | 4 | 07NOV2017 | . | . | Right | 1 | 15 | 12 | . | Yes | 0 grade | None |
| . | . | . | 5 | 15NOV2017 | . | . | Right | 1 | 14 | 12 | . | Yes | 0 grade | None |
| . | . | . | 6 | 29DEC2017 | . | . | Right | 1 | 14 | 13 | . | Yes | 0 grade | None |
| 100103 | | Female 70 | 1 | 27OCT2017 | 0.1 | 0.9 | . | . | . | 15 | 15 | Yes | 0 grade | None |
| 100104 | GEL | Male 70 | 1 | 03NOV2017 | 1 | 0.6 | . | . | . | 12 | 15 | Yes | 0 grade | None |
| . | . | . | 2 | 07NOV2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 08NOV2017 | . | . | Right | 0.8 | 12 | 17 | . | Yes | 0 grade | None |
| . | . | . | 4 | 14NOV2017 | . | . | Right | 1 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 5 | 22NOV2017 | . | . | Right | 1 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 6 | 05JAN2018 | . | . | Right | 1 | 16 | 15 | . | Yes | 0 grade | None |
| 100105 | DROP | Female 85 | 1 | 03NOV2017 | 0.5 | 1 | . | . | . | 13 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 08NOV2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 09NOV2017 | . | . | Left | 1 | 11 | 11 | . | Yes | 0 grade | None |
| . | . | . | 4 | 15NOV2017 | . | . | Left | 1 | 12 | 12 | . | Yes | 0 grade | None |
| . | . | . | 5 | 23NOV2017 | . | . | Left | 1 | 11 | 12 | . | Yes | 0 grade | None |
| . | . | . | 6 | 08JAN2018 | . | . | Left | 1 | 11 | 12 | . | Yes | 0 grade | None |
| 100106 | GEL | Male 56 | 1 | 09NOV2017 | 0.8 | 1 | . | . | . | 17 | 19 | Yes | 0 grade | None |
| . | . | . | 2 | 15NOV2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 16NOV2017 | . | . | Left | 1 | 17 | 18 | . | Yes | 0 grade | None |
| . | . | . | 4 | 22NOV2017 | . | . | Left | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 5 | 30NOV2017 | . | . | Left | 1 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 6 | 15JAN2018 | . | . | Left | 1 | 15 | 15 | . | Yes | 0 grade | None |

Listing 6 (2 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|------|---|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100107 | DROP | Female 82 | 1 | 23NOV2017 | 0.2 | 0.5 | . | . | 18 | 18 | Yes | 0 grade | None | |
| . | . | . | 2 | 28NOV2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 29NOV2017 | . | . | Left | 0.8 | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 4 | 05DEC2017 | . | . | Left | 1 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 5 | 13DEC2017 | . | . | Left | 1 | 14 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 26JAN2018 | . | . | Left | 1 | 14 | 15 | Yes | 0 grade | None | |
| 100108 | DROP | Female 73 | 1 | 01DEC2017 | 0.9 | 0.6 | . | . | 13 | 13 | Yes | 0 grade | None | |
| . | . | . | 2 | 06DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 07DEC2017 | . | . | Right | 1.2 | 13 | 12 | Yes | 0 grade | None | |
| . | . | . | 4 | 13DEC2017 | . | . | Right | 1.2 | 13 | 12 | Yes | 0 grade | None | |
| . | . | . | 5 | 21DEC2017 | . | . | Right | 1.2 | 12 | 12 | Yes | 0 grade | None | |
| . | . | . | 6 | 06FEB2018 | . | . | Right | 1.2 | 12 | 13 | Yes | 0 grade | None | |
| 100109 | GEL | Female 56 | 1 | 07DEC2017 | 1 | 0.9 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 12DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 13DEC2017 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 4 | 19DEC2017 | . | . | Right | 1.2 | 17 | 18 | Yes | 0 grade | None | |
| . | . | . | 5 | 27DEC2017 | . | . | Right | 1.2 | 17 | 18 | Yes | 0 grade | None | |
| . | . | . | 6 | 12FEB2018 | . | . | Right | 1.2 | 18 | 17 | Yes | 0 grade | None | |
| 100110 | DROP | Female 75 | 1 | 07DEC2017 | 0.6 | 0.6 | . | . | 14 | 15 | Yes | 0 grade | None | |
| . | . | . | 2 | 13DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 14DEC2017 | . | . | Right | 1.2 | 15 | 18 | Yes | 0 grade | None | |
| . | . | . | 4 | 20DEC2017 | . | . | Right | 1.2 | 15 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 28DEC2017 | . | . | Right | 1.2 | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 12FEB2018 | . | . | Right | 1.2 | 15 | 15 | Yes | 0 grade | None | |
| 100111 | DROP | Female 60 | 1 | 07DEC2017 | 0.5 | 1 | . | . | 16 | 15 | Yes | 0 grade | None | |
| . | . | . | 2 | 13DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 14DEC2017 | . | . | Left | 0.9 | 12 | 15 | Yes | 0 grade | None | |
| . | . | . | 4 | 20DEC2017 | . | . | Left | 1 | 13 | 15 | Yes | 0 grade | None | |
| . | . | . | 5 | 28DEC2017 | . | . | Left | 1 | 13 | 14 | Yes | 0 grade | None | |
| . | . | . | 6 | 12FEB2018 | . | . | Left | 1 | 13 | 14 | Yes | 0 grade | None | |

Listing 6 (3 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|----------------------|--------------|---------------|-----------|-----|-------|-----------------------|-----------|-----------|-----------|--|-------------------|------------------|
| | | | | Operated eye | | Eye | Value | Left eye | | Right eye | | Performed? | Cellul. grade* | Flare grade** |
| | | | | Left eye | Right eye | | | Left eye | Right eye | Left eye | Right eye | | | |
| 100112 | GEL | Male | 73 | 1 | 28DEC2017 | 0.6 | 0.2 | . | . | 14 | 15 | Yes | 0 grade | None |
| . | . | . | 2 | 03JAN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 04JAN2018 | . | . | Right | 0.8 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 4 | 10JAN2018 | . | . | Right | 1 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 5 | 17JAN2018 | . | . | Right | 1 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 6 | 05MAR2018 | . | . | Right | 1 | 15 | 15 | . | Yes | 0 grade | None |
| 100113 | GEL | Female | 77 | 1 | 28DEC2017 | 0.9 | 0.4 | . | . | 15 | 17 | Yes | 0 grade | None |
| . | . | . | 2 | 03JAN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 04JAN2018 | . | . | Right | 0.9 | 15 | 17 | . | Yes | 0 grade | None |
| . | . | . | 4 | 10JAN2018 | . | . | Right | 1 | 15 | 17 | . | Yes | 0 grade | None |
| . | . | . | 5 | 17JAN2018 | . | . | Right | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 6 | 05MAR2018 | . | . | Left | 1 | 16 | 16 | . | Yes | 0 grade | None |
| 100114 | GEL | Male | 64 | 1 | 29DEC2017 | 0.8 | 1 | . | . | 13 | 12 | Yes | 0 grade | None |
| . | . | . | 2 | 03JAN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 04JAN2018 | . | . | Left | 1 | 13 | 13 | . | Yes | 0 grade | None |
| . | . | . | 4 | 10JAN2018 | . | . | Left | 1 | 13 | 13 | . | Yes | 0 grade | None |
| . | . | . | 5 | 17JAN2018 | . | . | Left | 1 | 12 | 12 | . | Yes | 0 grade | None |
| . | . | . | 6 | 05MAR2018 | . | . | Left | 1 | 12 | 12 | . | Yes | 0 grade | None |
| 100115 | DROP | Male | 76 | 1 | 29DEC2017 | 0.7 | 0.6 | . | . | 15 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 04JAN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 05JAN2018 | . | . | Right | 1 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 4 | 11JAN2018 | . | . | Right | 1 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 5 | 18JAN2018 | . | . | Right | 1 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 6 | 06MAR2018 | . | . | Right | 1 | 15 | 15 | . | Yes | 0 grade | None |
| 100116 | GEL | Male | 62 | 1 | 29DEC2017 | 0.8 | 1 | . | . | 14 | 13 | Yes | 0 grade | None |
| . | . | . | 2 | 04JAN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 05JAN2018 | . | . | Left | 1 | 14 | 13 | . | Yes | 0 grade | None |
| . | . | . | 4 | 11JAN2018 | . | . | Left | 1 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 5 | 19JAN2018 | . | . | Left | 1 | 13 | 13 | . | Yes | 0 grade | None |
| . | . | . | 6 | 06MAR2018 | . | . | Left | 1 | 13 | 13 | . | Yes | 0 grade | None |

Listing 6 (4 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|-------------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|------|--|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100117 | DROP | Female 51 | 1 | 04JAN2018 | 0.7 | 1 | . | . | 16 | 15 | Yes | 0 grade | None | |
| . | . | . | 2 | 10JAN2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 11JAN2018 | . | . | Left | 1 | 18 | 15 | Yes | 0 grade | None | |
| . | . | . | 4 | 17JAN2018 | . | . | Left | 1 | 16 | 15 | Yes | 0 grade | None | |
| . | . | . | 5 | 23JAN2018 | . | . | Left | 1 | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 12MAR2018 | . | . | Left | 1 | 15 | 15 | Yes | 0 grade | None | |
| 100118 | DROP | Female 78 | 1 | 11JAN2018 | 0.7 | 0.6 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 17JAN2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 18JAN2018 | . | . | Right | 1 | 15 | 16 | Yes | 0 grade | None | |
| . | . | . | 4 | 24JAN2018 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 31JAN2018 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 19MAR2018 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None | |
| 100119 | DROP | Female 72 | 1 | 19JAN2018 | 0.5 | 0.2 | . | . | 19 | 19 | Yes | 0 grade | None | |
| . | . | . | 2 | 24JAN2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 25JAN2018 | . | . | Right | 1 | 19 | 19 | Yes | 0 grade | None | |
| . | . | . | 4 | 31JAN2018 | . | . | Right | 1 | 18 | 19 | Yes | 0 grade | None | |
| . | . | . | 5 | 08FEB2018 | . | . | Right | 0.6 | 18 | 19 | Yes | 0 grade | None | |
| . | . | . | 6 | 26MAR2018 | . | . | Right | 0.6 | 18 | 18 | Yes | 0 grade | None | |
| 100120 | GEL | Male 79 | 1 | 19JAN2018 | 0.3 | 1 | . | . | 18 | 15 | Yes | 0 grade | None | |
| . | . | . | 2 | 24JAN2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 25JAN2018 | . | . | Left | 0.8 | 16 | 15 | Yes | 0 grade | None | |
| . | . | . | 4 | 31JAN2018 | . | . | Left | 0.8 | 16 | 15 | Yes | 0 grade | None | |
| . | . | . | 5 | 07FEB2018 | . | . | Left | 0.8 | 16 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 26MAR2018 | . | . | Left | 0.8 | 15 | 15 | Yes | 0 grade | None | |
| 100121 | GEL | Male 80 | 1 | 19JAN2018 | 0.6 | 0.9 | . | . | 16 | 14 | Yes | 0 grade | None | |
| . | . | . | 2 | 24JAN2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 25JAN2018 | . | . | Left | 1 | 15 | 14 | Yes | 0 grade | None | |
| . | . | . | 4 | 31JAN2018 | . | . | Left | 1 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 5 | 07FEB2018 | . | . | Left | 1 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 6 | 26MAR2018 | . | . | Left | 1 | 14 | 14 | Yes | 0 grade | None | |

Listing 6 (5 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|------|--|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100122 | DROP | Female 76 | 1 | 19JAN2018 | 0.7 | 1 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 25JAN2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 26JAN2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 4 | 01FEB2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 08FEB2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 27MAR2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None | |
| 100123 | DROP | Female 76 | 1 | 19JAN2018 | 0.6 | 1 | . | . | 18 | 18 | Yes | 0 grade | None | |
| . | . | . | 2 | 25JAN2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 26JAN2018 | . | . | Left | 1 | 18 | 18 | Yes | 0 grade | None | |
| . | . | . | 4 | 01FEB2018 | . | . | Left | 1 | 18 | 18 | Yes | 0 grade | None | |
| . | . | . | 5 | 08FEB2018 | . | . | Left | 1 | 18 | 18 | Yes | 0 grade | None | |
| . | . | . | 6 | 27MAR2018 | . | . | Left | 1 | 18 | 18 | Yes | 0 grade | None | |
| 100124 | GEL | Female 71 | 1 | 26JAN2018 | 0.8 | 1 | . | . | 16 | 10 | Yes | 0 grade | None | |
| . | . | . | 2 | 01FEB2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 02FEB2018 | . | . | Left | 1 | 16 | 11 | Yes | 0 grade | None | |
| . | . | . | 4 | 08FEB2018 | . | . | Left | 1 | 16 | 11 | Yes | 0 grade | None | |
| . | . | . | 5 | 16FEB2018 | . | . | Left | 1 | 16 | 12 | Yes | 0 grade | None | |
| . | . | . | 6 | 03APR2018 | . | . | Left | 1 | 15 | 12 | Yes | 0 grade | None | |
| 100125 | GEL | Female 62 | 1 | 26JAN2018 | 0.3 | 1 | . | . | 19 | 18 | Yes | 0 grade | None | |
| . | . | . | 2 | 01FEB2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 02FEB2018 | . | . | Left | 1 | 18 | 18 | Yes | 0 grade | None | |
| . | . | . | 4 | 08FEB2018 | . | . | Left | 1 | 18 | 18 | Yes | 0 grade | None | |
| . | . | . | 5 | 16FEB2018 | . | . | Left | 1 | 17 | 17 | Yes | 0 grade | None | |
| . | . | . | 6 | 03APR2018 | . | . | Left | 1 | 17 | 17 | Yes | 0 grade | None | |
| 100126 | GEL | Female 85 | 1 | 02FEB2018 | 0.6 | 0.9 | . | . | 14 | 12 | Yes | 0 grade | None | |
| . | . | . | 2 | 07FEB2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 08FEB2018 | . | . | Left | 0.9 | 14 | 19 | Yes | 0 grade | None | |
| . | . | . | 4 | 14FEB2018 | . | . | Left | 0.9 | 14 | 18 | Yes | 0 grade | None | |
| . | . | . | 5 | 21FEB2018 | . | . | Left | 0.9 | 17 | 17 | Yes | 0 grade | None | |
| . | . | . | 6 | 09APR2018 | . | . | Left | 0.9 | 16 | 17 | Yes | 0 grade | None | |

Listing 6 (6 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|---------|------|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100127 | GEL | Female | 68 | 1 | 02FEB2018 | 1 | 0.6 | . | . | 15 | 18 | Yes | 0 grade | None |
| . | . | . | 2 | 08FEB2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 09FEB2018 | . | . | Right | 1 | 16 | 18 | . | Yes | 0 grade | None |
| . | . | . | 4 | 15FEB2018 | . | . | Right | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 5 | 24FEB2018 | . | . | Right | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 6 | 10APR2018 | . | . | Right | 1 | 16 | 16 | . | Yes | 0 grade | None |
| 100128 | DROP | Male | 80 | 1 | 02FEB2018 | 0.5 | 1 | . | . | 15 | 11 | Yes | 0 grade | None |
| . | . | . | 2 | 08FEB2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 09FEB2018 | . | . | Left | 1 | 16 | 11 | . | Yes | 0 grade | None |
| . | . | . | 4 | 15FEB2018 | . | . | Left | 1 | 16 | 11 | . | Yes | 0 grade | None |
| . | . | . | 5 | 24FEB2018 | . | . | Left | 1 | 16 | 12 | . | Yes | 0 grade | None |
| . | . | . | 6 | 10APR2018 | . | . | Left | 1 | 16 | 12 | . | Yes | 0 grade | None |
| 100129 | DROP | Female | 78 | 1 | 02FEB2018 | 0.5 | 0.5 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 08FEB2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 09FEB2018 | . | . | Left | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 4 | 15FEB2018 | . | . | Left | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 5 | 23FEB2018 | . | . | Left | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 6 | 10APR2018 | . | . | Left | 1 | 16 | 16 | . | Yes | 0 grade | None |
| 100130 | GEL | Male | 66 | 1 | 16FEB2018 | 0.5 | 0.5 | . | . | 15 | 18 | Yes | 0 grade | None |
| . | . | . | 2 | 21FEB2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 22FEB2018 | . | . | Left | 1 | 15 | 16 | . | Yes | 0 grade | None |
| . | . | . | 4 | 28FEB2018 | . | . | Left | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 5 | 07MAR2018 | . | . | Left | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 6 | 23APR2018 | . | . | Left | 1 | 15 | 15 | . | Yes | 0 grade | None |
| 100131 | DROP | Female | 77 | 1 | 16FEB2018 | 0.7 | 0.9 | . | . | 14 | 13 | Yes | 0 grade | None |
| . | . | . | 2 | 21FEB2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 22FEB2018 | . | . | Left | 0.9 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 4 | 28FEB2018 | . | . | Left | 1 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 5 | 07MAR2018 | . | . | Left | 1 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 6 | 23APR2018 | . | . | Left | 1 | 12 | 12 | . | Yes | 0 grade | None |

Listing 6 (7 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|---------|------|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100132 | DROP | Male | 69 | 1 | 02MAR2018 | 1 | 0.6 | . | . | 17 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 07MAR2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 08MAR2018 | . | . | Right | 1 | 18 | 16 | Yes | 0 grade | None | |
| . | . | . | 4 | 14MAR2018 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 21MAR2018 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 08MAY2018 | . | . | Right | 1 | 14 | 15 | Yes | 0 grade | None | |
| 100133 | GEL | Male | 74 | 1 | 02MAR2018 | 0.5 | 0.7 | . | . | 15 | 15 | Yes | 0 grade | None |
| . | . | . | 2 | 07MAR2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 08MAR2018 | . | . | Left | 1 | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 4 | 14MAR2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 21MAR2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 08MAY2018 | . | . | Left | 1 | 15 | 14 | Yes | 0 grade | None | |
| 100134 | DROP | Female | 66 | 1 | 02MAR2018 | 1 | 0.3 | . | . | 13 | 12 | Yes | 0 grade | None |
| . | . | . | 2 | 07MAR2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 08MAR2018 | . | . | Left | 1 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 4 | 14MAR2018 | . | . | Left | 1 | 13 | 13 | Yes | 0 grade | None | |
| . | . | . | 5 | 21MAR2018 | . | . | Left | 1 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 6 | 08MAY2018 | . | . | Left | 1 | 15 | 14 | Yes | 0 grade | None | |
| 100135 | GEL | Male | 69 | 1 | 09MAR2018 | 1 | 0.4 | . | . | 19 | 19 | Yes | 0 grade | None |
| . | . | . | 2 | 15MAR2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 16MAR2018 | . | . | Right | 1 | 19 | 18 | Yes | 0 grade | None | |
| . | . | . | 4 | 22MAR2018 | . | . | Right | 1 | 19 | 18 | Yes | 0 grade | None | |
| . | . | . | 5 | 29MAR2018 | . | . | Right | 1 | 18 | 18 | Yes | 0 grade | None | |
| . | . | . | 6 | 15MAY2018 | . | . | Right | 1 | 17 | 17 | Yes | 0 grade | None | |
| 100136 | GEL | Female | 90 | 1 | 30MAR2018 | 0.3 | 0.4 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 05APR2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 06APR2018 | . | . | Left | 0.8 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 4 | 12APR2018 | . | . | Left | 0.8 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 20APR2018 | . | . | Left | 0.8 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 06JUN2018 | . | . | Left | 0.8 | 16 | 16 | Yes | 0 grade | None | |

Listing 6 (8 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|---------|------|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100137 | DROP | Female | 62 | 1 | 13APR2018 | 1 | 0.8 | . | . | 18 | 16 | Yes | 0 grade | None |
| . | . | . | . | 2 | 19APR2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 20APR2018 | . | . | Right | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 4 | 26APR2018 | . | . | Right | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 5 | 04MAY2018 | . | . | Right | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 6 | 19JUN2018 | . | . | Right | 1 | 16 | 16 | . | Yes | 0 grade | None |
| 100138 | GEL | Male | 63 | 1 | 13APR2018 | 0.9 | 0.8 | . | . | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 19APR2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 20APR2018 | . | . | Right | 1 | 14 | 15 | . | Yes | 0 grade | None |
| . | . | . | 4 | 26APR2018 | . | . | Right | 1 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 5 | 04MAY2018 | . | . | Right | 1 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 6 | 19JUN2018 | . | . | Right | 1 | 15 | 15 | . | Yes | 0 grade | None |
| 100139 | DROP | Female | 71 | 1 | 20APR2018 | 0.7 | 0.6 | . | . | 12 | 11 | Yes | 0 grade | None |
| . | . | . | 2 | 26APR2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 27APR2018 | . | . | Right | 1 | 12 | 13 | . | Yes | 0 grade | None |
| . | . | . | 4 | 03MAY2018 | . | . | Right | 1 | 13 | 13 | . | Yes | 0 grade | None |
| . | . | . | 5 | 11MAY2018 | . | . | Right | 1 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 6 | 26JUN2018 | . | . | Right | 1 | 15 | 14 | . | Yes | 0 grade | None |
| 100140 | GEL | Male | 81 | 1 | 27APR2018 | 0.7 | 0.6 | . | . | 15 | 12 | Yes | 0 grade | None |
| . | . | . | 2 | 02MAY2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 03MAY2018 | . | . | Right | 1 | 15 | 13 | . | Yes | 0 grade | None |
| . | . | . | 4 | 09MAY2018 | . | . | Right | 1 | 15 | 12 | . | Yes | 0 grade | None |
| . | . | . | 5 | 17MAY2018 | . | . | Right | 1 | 14 | 12 | . | Yes | 0 grade | None |
| . | . | . | 6 | 02JUL2018 | . | . | Right | 1 | 14 | 12 | . | Yes | 0 grade | None |
| 100141 | DROP | Female | 74 | 1 | 27APR2018 | 0.9 | 0.6 | . | . | 15 | 17 | Yes | 0 grade | None |
| . | . | . | 2 | 02MAY2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 03MAY2018 | . | . | Right | 1 | 14 | 15 | . | Yes | 0 grade | None |
| . | . | . | 4 | 10MAY2018 | . | . | Right | 1 | 14 | 12 | . | Yes | 0 grade | None |
| . | . | . | 5 | 16MAY2018 | . | . | Right | 1 | 13 | 12 | . | Yes | 0 grade | None |
| . | . | . | 6 | 02JUL2018 | . | . | Right | 1 | 12 | 12 | . | Yes | 0 grade | None |

Listing 6 (9 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|---------|------|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100142 | GEL | Female | 77 | 1 | 11MAY2018 | 0.7 | 0.9 | . | . | 16 | 17 | Yes | 0 grade | None |
| . | . | . | 2 | 16MAY2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 17MAY2018 | . | . | Left | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 4 | 23MAY2018 | . | . | Left | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 5 | 31MAY2018 | . | . | Left | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 6 | 16JUL2018 | . | . | Left | 1 | 16 | 16 | . | Yes | 0 grade | None |
| 100143 | GEL | Male | 74 | 1 | 15JUN2018 | 0.4 | 0.7 | . | . | 15 | 15 | Yes | 0 grade | None |
| . | . | . | 2 | 20JUN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 21JUN2018 | . | . | Left | 1 | 16 | 15 | . | Yes | 0 grade | None |
| . | . | . | 4 | 27JUN2018 | . | . | Left | 1 | 16 | 15 | . | Yes | 0 grade | None |
| . | . | . | 5 | 04JUL2018 | . | . | Left | 1 | 17 | 15 | . | Yes | 0 grade | None |
| . | . | . | 6 | 20AUG2018 | . | . | Left | 1 | 16 | 15 | . | Yes | 0 grade | None |
| 100144 | DROP | Female | 89 | 1 | 22JUN2018 | 0.3 | 0.2 | . | . | 14 | 13 | Yes | 0 grade | None |
| . | . | . | 2 | 27JUN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 28JUN2018 | . | . | Right | 0.8 | 14 | 12 | . | Yes | 0 grade | None |
| . | . | . | 4 | 04JUL2018 | . | . | Right | 0.8 | 13 | 12 | . | Yes | 0 grade | None |
| . | . | . | 5 | 12JUL2018 | . | . | Right | 0.8 | 13 | 12 | . | Yes | 0 grade | None |
| . | . | . | 6 | 27AUG2018 | . | . | Right | 0.8 | 13 | 12 | . | Yes | 0 grade | None |
| 100145 | GEL | Male | 81 | 1 | 29JUN2018 | 0.9 | 0.6 | . | . | 12 | 12 | Yes | 0 grade | None |
| . | . | . | 2 | 04JUL2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 05JUL2018 | . | . | Right | 1 | 12 | 12 | . | Yes | 0 grade | None |
| . | . | . | 4 | 11JUL2018 | . | . | Right | 1 | 12 | 13 | . | Yes | 0 grade | None |
| . | . | . | 5 | 18JUL2018 | . | . | Right | 1 | 12 | 12 | . | Yes | 0 grade | None |
| . | . | . | 6 | 04SEP2018 | . | . | Right | 1 | 13 | 12 | . | Yes | 0 grade | None |
| 100146 | GEL | Male | 71 | 1 | 17AUG2018 | 1 | 0.6 | . | . | 18 | 18 | Yes | 0 grade | None |
| . | . | . | 2 | 21AUG2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 22AUG2018 | . | . | Right | 1 | 18 | 17 | . | Yes | 0 grade | None |
| . | . | . | 4 | 29AUG2018 | . | . | Right | 1 | 18 | 17 | . | Yes | 0 grade | None |
| . | . | . | 5 | 06SEP2018 | . | . | Right | 1 | 18 | 17 | . | Yes | 0 grade | None |
| . | . | . | 6 | 22OCT2018 | . | . | Right | 1 | 17 | 17 | . | Yes | 0 grade | None |
| 100147 | DROP | Male | 48 | 1 | 24AUG2018 | 1 | 0.4 | . | . | 17 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 28AUG2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 29AUG2018 | . | . | Right | 1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 4 | 20SEP2018 | . | . | Right | 1 | 16 | 16 | . | Yes | 0 grade | None |

Listing 6 (10 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|---------|------|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100148 | DROP | Female | 83 | 1 | 24AUG2018 | 0.7 | 1 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 2 | 30AUG2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 31AUG2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 4 | 06SEP2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 5 | 13SEP2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 6 | 29OCT2018 | . | . | Left | 1 | 15 | 15 | Yes | 0 grade | None |
| 100149 | DROP | Female | 71 | 1 | 24AUG2018 | 1 | 0.7 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 2 | 30AUG2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 31AUG2018 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 4 | 06SEP2018 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 5 | 15SEP2018 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 6 | 29OCT2018 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None |
| 100150 | GEL | Female | 77 | 1 | 31AUG2018 | 1 | 0.4 | . | . | 16 | 15 | Yes | 0 grade | None |
| . | . | . | . | 2 | 05SEP2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 06SEP2018 | . | . | Right | 1 | 16 | 14 | Yes | 0 grade | None |
| . | . | . | . | 4 | 12SEP2018 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 5 | 21SEP2018 | . | . | Right | 1 | 15 | 16 | Yes | 0 grade | None |
| . | . | . | . | 6 | 05NOV2018 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None |
| 100151 | DROP | Female | 67 | 1 | 28SEP2018 | 0.6 | 0.7 | . | . | 18 | 18 | Yes | 0 grade | None |
| . | . | . | . | 2 | 04OCT2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 05OCT2018 | . | . | Left | 1 | 18 | 17 | Yes | 0 grade | None |
| . | . | . | . | 4 | 12OCT2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 5 | 20OCT2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 6 | 04DEC2018 | . | . | Left | 1 | 15 | 15 | Yes | 0 grade | None |
| 100152 | GEL | Female | 78 | 1 | 28SEP2018 | 0.7 | 0.6 | . | . | 18 | 18 | Yes | 0 grade | None |
| . | . | . | . | 2 | 04OCT2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 05OCT2018 | . | . | Left | 0.7 | 17 | 18 | Yes | 0 grade | None |
| . | . | . | . | 4 | 12OCT2018 | . | . | Left | 0.7 | 17 | 17 | Yes | 0 grade | None |
| . | . | . | . | 5 | 20OCT2018 | . | . | Left | 0.7 | 16 | 17 | Yes | 0 grade | None |
| 100153 | DROP | Female | 81 | 1 | 12OCT2018 | 0.4 | 0.5 | . | . | 12 | 17 | Yes | 0 grade | None |
| . | . | . | . | 2 | 17OCT2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 18OCT2018 | . | . | Left | 0.8 | 16 | 13 | Yes | 0 grade | None |
| . | . | . | . | 4 | 24OCT2018 | . | . | Left | 0.8 | 16 | 13 | Yes | 0 grade | None |
| . | . | . | . | 5 | 29OCT2018 | . | . | Left | 0.8 | 16 | 13 | Yes | 0 grade | None |
| . | . | . | . | 6 | 18DEC2018 | . | . | Left | 0.8 | 15 | 13 | Yes | 0 grade | None |

Listing 6 (11 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|-------|--|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100154 | GEL | Female 68 | 1 | 12OCT2018 | 1 | 0.6 | . | . | 18 | 18 | Yes | 0 grade | None | |
| . | . | . | 2 | 18OCT2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 19OCT2018 | . | . | Right | 1 | 18 | 18 | Yes | 0 grade | None | |
| . | . | . | 4 | 26OCT2018 | . | . | Right | 1 | 18 | 18 | Yes | 0.5 grade | None | |
| . | . | . | 5 | 02NOV2018 | . | . | Right | 1 | 18 | 18 | Yes | 0 grade | None | |
| . | . | . | 6 | 18DEC2018 | . | . | Right | 1 | 17 | 17 | Yes | 0 grade | None | |
| 100155 | DROP | Female 79 | 1 | 12OCT2018 | 0.4 | 0.5 | . | . | 19 | 19 | Yes | 0 grade | None | |
| . | . | . | 2 | 18OCT2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 19OCT2018 | . | . | Left | 0.8 | 19 | 19 | Yes | 0 grade | None | |
| . | . | . | 4 | 26OCT2018 | . | . | Left | 0.8 | 18 | 18 | Yes | 0 grade | None | |
| . | . | . | 5 | 02NOV2018 | . | . | Left | 0.8 | 17 | 17 | Yes | 0 grade | None | |
| . | . | . | 6 | 18DEC2018 | . | . | Left | 0.8 | 17 | 17 | Yes | 0 grade | None | |
| 100156 | GEL | Female 69 | 1 | 12OCT2018 | 0.9 | 0.8 | . | . | 19 | 19 | Yes | 0 grade | None | |
| . | . | . | 2 | 18OCT2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 19OCT2018 | . | . | Right | 0.9 | 19 | 19 | Yes | 0 grade | None | |
| . | . | . | 4 | 26OCT2018 | . | . | Right | 0.9 | 19 | 19 | Yes | 0 grade | None | |
| . | . | . | 5 | 02NOV2018 | . | . | Right | 1 | 18 | 18 | Yes | 0 grade | None | |
| . | . | . | 6 | 18DEC2018 | . | . | Right | 1 | 18 | 18 | Yes | 0 grade | None | |
| 100201 | GEL | Female 80 | 1 | 01DEC2017 | 0.8 | 0.3 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 07DEC2017 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 09DEC2017 | . | . | Right | 0.5 | 14 | 15 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 13DEC2017 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | Faint | |
| . | . | . | 5 | 22DEC2017 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 08FEB2018 | . | . | Right | 1 | 15 | 15 | Yes | 0 grade | None | |
| 100202 | DROP | Female 70 | 1 | 01DEC2017 | 0.7 | 0.5 | . | . | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 2 | 07DEC2017 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 09DEC2017 | . | . | Right | 0.7 | 16 | 16 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 14DEC2017 | . | . | Right | 1 | 12 | 12 | Yes | 0 grade | None | |
| . | . | . | 5 | 20DEC2017 | . | . | Right | 1 | 12 | 12 | Yes | 0 grade | None | |
| . | . | . | 6 | 08FEB2018 | . | . | Right | 1 | 12 | 12 | Yes | 0 grade | None | |

Listing 6 (12 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|---------|------|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100203 | DROP | Female | 76 | 1 | 07DEC2017 | 0.9 | 0.3 | . | . | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 14DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 15DEC2017 | . | . | Right | 0.7 | 14 | 14 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 20DEC2017 | . | . | Right | 0.95 | 12 | 12 | Yes | 0 grade | None | |
| . | . | . | 5 | 28DEC2017 | . | . | Right | 0.95 | 12 | 12 | Yes | 0 grade | None | |
| . | . | . | 6 | 15FEB2018 | . | . | Right | 0.95 | 12 | 12 | Yes | 0 grade | None | |
| 100204 | GEL | Male | 71 | 1 | 07DEC2017 | 0.6 | 0.2 | . | . | 19 | 19 | Yes | 0 grade | None |
| . | . | . | 2 | 14DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 15DEC2017 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 20DEC2017 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 28DEC2017 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 15FEB2018 | . | . | Right | 1 | 15 | 15 | Yes | 0 grade | None | |
| 100205 | GEL | Male | 75 | 1 | 14DEC2017 | 0.5 | 0.8 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 08FEB2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 09FEB2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 14FEB2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 21FEB2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 09APR2018 | . | . | Left | 1 | 15 | 15 | Yes | 0 grade | None | |
| 100206 | DROP | Female | 81 | 1 | 05JAN2018 | 0.8 | 0.4 | . | . | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 11JAN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 12JAN2018 | . | . | Right | 0.8 | 14 | 14 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 18JAN2018 | . | . | Right | 0.9 | 14 | 14 | Yes | 0 grade | Faint | |
| . | . | . | 5 | 24JAN2018 | . | . | Right | 0.95 | 13 | 13 | Yes | 0 grade | None | |
| . | . | . | 6 | 14MAR2018 | . | . | Right | 0.95 | 14 | 14 | Yes | 0 grade | None | |
| 100207 | DROP | Female | 65 | 1 | 05JAN2018 | 0.6 | 0.4 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 11JAN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 12JAN2018 | . | . | Right | 0.8 | 14 | 14 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 18JAN2018 | . | . | Right | 1 | 14 | 14 | Yes | 0 grade | Faint | |
| . | . | . | 5 | 24JAN2018 | . | . | Right | 1 | 13 | 13 | Yes | 0 grade | None | |
| . | . | . | 6 | 14MAR2018 | . | . | Right | 1 | 14 | 14 | Yes | 0 grade | None | |

Listing 6 (13 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|-------|---|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100208 | GEL | Female 79 | 1 | 05JAN2018 | 0.8 | 0.6 | . | . | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 2 | 11JAN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 12JAN2018 | . | . | Right | 0.8 | 14 | 14 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 18JAN2018 | . | . | Right | 1 | 14 | 14 | Yes | 0 grade | Faint | |
| . | . | . | 5 | 31JAN2018 | . | . | Right | 0.95 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 6 | 14MAR2018 | . | . | Right | 0.95 | 14 | 14 | Yes | 0 grade | None | |
| 100209 | GEL | Female 77 | 1 | 12JAN2018 | 0.6 | 0.4 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 18JAN2018 | . | . | . | . | . | . | . | . | . | |
| 100210 | DROP | Female 70 | 1 | 12JAN2018 | 1 | 0.4 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 18JAN2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 19JAN2018 | . | . | Right | 0.8 | 14 | 14 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 24JAN2018 | . | . | Right | 1 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 5 | 31JAN2018 | . | . | Right | 1 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 6 | 22MAR2018 | . | . | Right | 1 | 14 | 14 | Yes | 0 grade | None | |
| 100211 | GEL | Male 67 | 1 | 12JAN2018 | 0.4 | 0.8 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 18JAN2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 19JAN2018 | . | . | Left | 0.6 | 16 | 16 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 24JAN2018 | . | . | Left | 0.9 | 16 | 16 | Yes | 0 grade | Faint | |
| . | . | . | 5 | 31JAN2018 | . | . | Left | 0.9 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 22MAR2018 | . | . | Left | 0.9 | 15 | 15 | Yes | 0 grade | None | |
| 100212 | DROP | Female 82 | 1 | 12JAN2018 | 0.4 | 1 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 18JAN2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 19JAN2018 | . | . | Left | 0.8 | 16 | 16 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 24JAN2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | Faint | |
| . | . | . | 5 | 31JAN2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 22MAR2018 | . | . | Left | 1 | 14 | 14 | Yes | 0 grade | None | |
| 100213 | DROP | Female 81 | 1 | 25JAN2018 | 0.4 | 1 | . | . | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 2 | 01FEB2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 02FEB2018 | . | . | Left | 0.8 | 15 | 15 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 07FEB2018 | . | . | Left | 1 | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 5 | 16FEB2018 | . | . | Left | 1 | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 04APR2018 | . | . | Left | 1 | 14 | 14 | Yes | 0 grade | None | |

Listing 6 (14 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | | |
|-------------|---------------|-------------------|--------------|---------------|-----------|-----|-------|-----------------------|-----------|-----------|-----------|--|-------------------|------------------|-------|
| | | | | Operated eye | | Eye | Value | Left eye | | Right eye | | Performed? | Cellul. grade* | Flare grade** | |
| | | | | Left eye | Right eye | | | Left eye | Right eye | Left eye | Right eye | | | | |
| 100214 | DROP | Female 77 | 1 | 05FEB2018 | 0.5 | 1 | . | . | 16 | 16 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 08FEB2018 | . | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 09FEB2018 | . | . | Left | 0.8 | 16 | 16 | 16 | 16 | Yes | 0 grade | Faint |
| . | . | . | 4 | 14FEB2018 | . | . | Left | 1 | 15 | 15 | 15 | 15 | Yes | 0 grade | None |
| . | . | . | 5 | 21FEB2018 | . | . | Left | 1 | 15 | 15 | 15 | 15 | Yes | 0 grade | None |
| . | . | . | 6 | 09APR2018 | . | . | Left | 1 | 14 | 14 | 14 | 14 | Yes | 0 grade | None |
| 100215 | GEL | Female 83 | 1 | 05FEB2018 | 0.5 | 0.6 | . | . | 15 | 15 | 15 | 15 | Yes | 0 grade | None |
| . | . | . | 2 | 08FEB2018 | . | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 09FEB2018 | . | . | Left | 0.8 | 15 | 15 | 15 | 15 | Yes | 0 grade | Faint |
| . | . | . | 4 | 14FEB2018 | . | . | Left | 0.9 | 12 | 15 | 15 | 15 | Yes | 0 grade | None |
| . | . | . | 5 | 21FEB2018 | . | . | Left | 0.9 | 14 | 14 | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 6 | 09APR2018 | . | . | Left | 0.9 | 14 | 14 | 14 | 14 | Yes | 0 grade | None |
| 100216 | GEL | Female 74 | 1 | 09FEB2018 | 0.5 | 1 | . | . | 16 | 16 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 15FEB2018 | . | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 16FEB2018 | . | . | Left | 0.9 | 15 | 15 | 15 | 15 | Yes | 0 grade | Faint |
| . | . | . | 4 | 21FEB2018 | . | . | Left | 1 | 16 | 16 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 5 | 28FEB2018 | . | . | Left | 1 | 14 | 14 | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 6 | 16APR2018 | . | . | Left | 1 | 14 | 14 | 14 | 14 | Yes | 0 grade | None |
| 100217 | DROP | Female 72 | 1 | 02MAR2018 | 1 | 0.5 | . | . | 13 | 13 | 13 | 13 | Yes | 0 grade | None |
| . | . | . | 2 | 08MAR2018 | . | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 09MAR2018 | . | . | Right | 0.8 | 13 | 13 | 13 | 13 | Yes | 0 grade | Faint |
| . | . | . | 4 | 14MAR2018 | . | . | Right | 1 | 14 | 14 | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 5 | 21MAR2018 | . | . | Right | 1 | 14 | 14 | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 6 | 08MAY2018 | . | . | Right | 1 | 14 | 14 | 14 | 14 | Yes | 0 grade | None |
| 100218 | DROP | Male 72 | 1 | 02MAR2018 | 1 | 0.5 | . | . | 13 | 13 | 13 | 13 | Yes | 0 grade | None |
| . | . | . | 2 | 08MAR2018 | . | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 09MAR2018 | . | . | Right | 0.7 | 13 | 13 | 13 | 13 | Yes | 0 grade | Faint |
| . | . | . | 4 | 14MAR2018 | . | . | Right | 1 | 15 | 15 | 15 | 15 | Yes | 0 grade | None |
| . | . | . | 5 | 21MAR2018 | . | . | Right | 1 | 14 | 14 | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 6 | 08MAY2018 | . | . | Right | 1 | 17 | 17 | 17 | 17 | Yes | 0 grade | None |

Listing 6 (15 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|---------|-------|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100219 | GEL | Female | 83 | 1 | 09MAR2018 | 0.5 | 0.5 | . | . | 13 | 13 | Yes | 0 grade | None |
| . | . | . | . | 2 | 15MAR2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 16MAR2018 | . | . | Right | 0.7 | 13 | 13 | Yes | 0 grade | Faint |
| . | . | . | . | 4 | 21MAR2018 | . | . | Right | 0.8 | 14 | 14 | Yes | 0 grade | Faint |
| . | . | . | . | 5 | 28MAR2018 | . | . | Right | 0.8 | 13 | 13 | Yes | 0 grade | None |
| . | . | . | . | 6 | 16MAY2018 | . | . | Right | 0.8 | 14 | 14 | Yes | 0 grade | None |
| 100220 | GEL | Male | 64 | 1 | 09MAR2018 | 0.4 | 1 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 2 | 15MAR2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 16MAR2018 | . | . | Left | 0.8 | 14 | 14 | Yes | 0 grade | Faint |
| . | . | . | . | 4 | 21MAR2018 | . | . | Left | 0.9 | 13 | 13 | Yes | 0 grade | Faint |
| . | . | . | . | 5 | 28MAR2018 | . | . | Left | 0.9 | 13 | 13 | Yes | 0 grade | None |
| . | . | . | . | 6 | 16MAY2018 | . | . | Left | 0.9 | 14 | 14 | Yes | 0 grade | None |
| 100221 | GEL | Female | 76 | 1 | 30MAR2018 | 0.6 | 0.4 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 2 | 05APR2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 06APR2018 | . | . | Right | 0.7 | 13 | 18 | Yes | 0 grade | Faint |
| . | . | . | . | 4 | 11APR2018 | . | . | Right | 1 | 14 | 18 | Yes | 0 grade | None |
| . | . | . | . | 5 | 20APR2018 | . | . | Right | 1 | 14 | 16 | Yes | 0 grade | None |
| . | . | . | . | 6 | 01JUN2018 | . | . | Right | 1 | 14 | 14 | Yes | 0 grade | None |
| 100222 | DROP | Female | 76 | 1 | 05APR2018 | 0.3 | 1 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 2 | 12APR2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 13APR2018 | . | . | Left | 0.7 | 16 | 16 | Yes | 0 grade | Faint |
| . | . | . | . | 4 | 18APR2018 | . | . | Left | 0.9 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 5 | 26APR2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 6 | 14JUN2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None |
| 100223 | DROP | Male | 61 | 1 | 05APR2018 | 0.6 | 0.65 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 2 | 12APR2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 13APR2018 | . | . | Left | 0.8 | 16 | 16 | Yes | 0 grade | Faint |
| . | . | . | . | 4 | 18APR2018 | . | . | Left | 0.95 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 5 | 26APR2018 | . | . | Left | 0.95 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 6 | 14JUN2018 | . | . | Left | 0.95 | 15 | 15 | Yes | 0 grade | None |

Listing 6 (16 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|-------|---|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100224 | GEL | Female 75 | 1 | 20APR2018 | 0.5 | 0.4 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 26APR2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 27APR2018 | . | . | Right | 0.8 | 16 | 16 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 02MAY2018 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 09MAY2018 | . | . | Right | 1 | 16 | 14 | Yes | 0 grade | None | |
| . | . | . | 6 | 27JUN2018 | . | . | Right | 1 | 14 | 14 | Yes | 0 grade | None | |
| 100225 | DROP | Female 79 | 1 | 20APR2018 | 0.1 | 0.6 | . | . | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 2 | 26APR2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 27APR2018 | . | . | Right | 0.9 | 13 | 13 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 02MAY2018 | . | . | Right | 1 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 5 | 09MAY2018 | . | . | Right | 1 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 6 | 27JUN2018 | . | . | Right | 1 | 14 | 14 | Yes | 0 grade | None | |
| 100226 | GEL | Female 74 | 1 | 20APR2018 | 1 | 0.4 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 26APR2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 27APR2018 | . | . | Right | 0.8 | 16 | 16 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 02MAY2018 | . | . | Right | 0.9 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 09MAY2018 | . | . | Right | 0.9 | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 27JUN2018 | . | . | Right | 0.9 | 15 | 15 | Yes | 0 grade | None | |
| 100227 | DROP | Female 68 | 1 | 27APR2018 | 0.4 | 1 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 03MAY2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 04MAY2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 09MAY2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 16MAY2018 | . | . | Left | 1 | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 04JUL2018 | . | . | Left | 1 | 15 | 15 | Yes | 0 grade | None | |
| 100228 | GEL | Female 68 | 1 | 27APR2018 | 1 | 0.7 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 03MAY2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 04MAY2018 | . | . | Right | 0.8 | 16 | 16 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 09MAY2018 | . | . | Right | 0.95 | 16 | 16 | Yes | 0 grade | None | |
| 100229 | GEL | Female 70 | 1 | 04MAY2018 | 0.5 | 0.7 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 10MAY2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 11MAY2018 | . | . | Left | 0.8 | 16 | 15 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 16MAY2018 | . | . | Left | 1 | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 5 | 23MAY2018 | . | . | Left | 1 | 14 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 10JUL2018 | . | . | Left | 1 | 14 | 14 | Yes | 0 grade | None | |

Listing 6 (17 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|---------|------|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100230 | GEL | Female | 63 | 1 | 04MAY2018 | 0.6 | 0.9 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 10MAY2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 11MAY2018 | . | . | Left | 0.9 | 15 | 15 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 16MAY2018 | . | . | Left | 1 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 5 | 23MAY2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 11JUL2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None | |
| 100231 | DROP | Female | 74 | 1 | 04MAY2018 | 0.8 | 0.4 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 10MAY2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 11MAY2018 | . | . | Right | 0.8 | 15 | 15 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 16MAY2018 | . | . | Right | 0.95 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 5 | 23MAY2018 | . | . | Right | 1 | 16 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 06JUL2018 | . | . | Right | 1 | 15 | 15 | Yes | 0 grade | None | |
| 100232 | DROP | Female | 73 | 1 | 04MAY2018 | 0.5 | 0.9 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 10MAY2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 11MAY2018 | . | . | Left | 0.8 | 15 | 15 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 16MAY2018 | . | . | Left | 1 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 5 | 23MAY2018 | . | . | Left | 1 | 14 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 06JUL2018 | . | . | Left | 1 | 15 | 14 | Yes | 0 grade | None | |
| . | . | . | 7 | . | . | . | . | . | . | . | . | . | . | . |
| 100233 | GEL | Female | 72 | 1 | 18MAY2018 | 0.3 | 1 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 24MAY2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 25MAY2018 | . | . | Left | 0.8 | 15 | 15 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 30MAY2018 | . | . | Left | 0.8 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 06JUN2018 | . | . | Left | 0.9 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 20JUL2018 | . | . | Left | 0.9 | 16 | 16 | Yes | 0 grade | None | |
| 100234 | GEL | Female | 73 | 1 | 18MAY2018 | 1 | 0.5 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 24MAY2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 25MAY2018 | . | . | Right | 0.8 | 15 | 13 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 30MAY2018 | . | . | Right | 1 | 13 | 13 | Yes | 0 grade | None | |
| . | . | . | 5 | 06JUN2018 | . | . | Right | 1 | 13 | 13 | Yes | 0 grade | None | |
| . | . | . | 6 | 20JUL2018 | . | . | Right | 1 | 13 | 13 | Yes | 0 grade | None | |

Listing 6 (18 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|-----|-------|-----------------------|-----------|-----------|-----------|--|-------------------|------------------|
| | | | | Operated eye | | Eye | Value | Left eye | | Right eye | | Performed? | Cellul. grade* | Flare grade** |
| | | | | Left eye | Right eye | | | Left eye | Right eye | Left eye | Right eye | | | |
| 100235 | DROP | Male | 64 | 1 | 28MAY2018 | 1 | 0.2 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 31MAY2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 01JUN2018 | . | . | Right | 0.6 | 15 | 14 | . | Yes | 0 grade | Faint |
| . | . | . | 4 | 06JUN2018 | . | . | Right | 0.7 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 5 | 13JUN2018 | . | . | Right | 0.8 | 13 | 13 | . | Yes | 0 grade | None |
| . | . | . | 6 | 01AUG2018 | . | . | Right | 0.85 | 13 | 13 | . | Yes | 0 grade | None |
| 100236 | DROP | Female | 70 | 1 | 28MAY2018 | 0.6 | 0.3 | . | . | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 31MAY2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 01JUN2018 | . | . | Right | 0.7 | 14 | 15 | . | Yes | 0 grade | Faint |
| . | . | . | 4 | 06JUN2018 | . | . | Right | 1 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 5 | 13JUN2018 | . | . | Right | 1 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 6 | 01AUG2018 | . | . | Right | 1 | 14 | 14 | . | Yes | 0 grade | None |
| 100237 | DROP | Male | 73 | 1 | 01JUN2018 | 0.4 | 0.6 | . | . | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 07JUN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 08JUN2018 | . | . | Left | 0.6 | 14 | 14 | . | Yes | 0 grade | Faint |
| . | . | . | 4 | 13JUN2018 | . | . | Left | 0.8 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 5 | 20JUN2018 | . | . | Left | 0.8 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 6 | 06AUG2018 | . | . | Left | 0.85 | 14 | 14 | . | Yes | 0 grade | None |
| 100238 | GEL | Male | 78 | 1 | 01JUN2018 | 1 | 0.3 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 07JUN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 08JUN2018 | . | . | Right | 0.6 | 14 | 16 | . | Yes | 0 grade | Faint |
| . | . | . | 4 | 13JUN2018 | . | . | Right | 0.8 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 5 | 20JUN2018 | . | . | Right | 0.8 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 6 | 06AUG2018 | . | . | Right | 0.9 | 14 | 14 | . | Yes | 0 grade | None |
| 100239 | DROP | Female | 80 | 1 | 08JUN2018 | 0.8 | 0.3 | . | . | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 14JUN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 15JUN2018 | . | . | Right | 0.7 | 14 | 15 | . | Yes | 0 grade | Faint |
| . | . | . | 4 | 20JUN2018 | . | . | Right | 1 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 5 | 27JUN2018 | . | . | Right | 1 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 6 | 14AUG2018 | . | . | Right | 1 | 14 | 14 | . | Yes | 0 grade | None |
| 100240 | | Female | 72 | 1 | 06JUL2018 | 0.5 | 1 | . | . | 16 | 16 | Yes | 0 grade | None |

Listing 6 (19 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|-------------------|--------------|---------------|-----------|-----|-------|-----------------------|-----------|-----------|-----------|--|-------------------|------------------|
| | | | | Operated eye | | Eye | Value | Left eye | | Right eye | | Performed? | Cellul. grade* | Flare grade** |
| | | | | Left eye | Right eye | | | Left eye | Right eye | Left eye | Right eye | | | |
| 100241 | GEL | Female 74 | 1 | 23OCT2018 | 0.6 | 0.7 | . | . | 13 | 13 | Yes | 0 grade | None | |
| . | . | . | 2 | 25OCT2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 26OCT2018 | . | . | Left | 0.7 | 14 | 14 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 31OCT2018 | . | . | Left | 1 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 5 | 07NOV2018 | . | . | Left | 1 | 13 | 14 | Yes | 0 grade | None | |
| . | . | . | 6 | 24DEC2018 | . | . | Left | 1 | 14 | 14 | Yes | 0 grade | None | |
| 100242 | GEL | Female 67 | 1 | 31OCT2018 | 0.8 | 0.6 | . | . | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 2 | 08NOV2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 09NOV2018 | . | . | Right | 0.8 | 14 | 15 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 14NOV2018 | . | . | Right | 0.95 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 5 | 22NOV2018 | . | . | Right | 0.95 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 6 | 12JAN2019 | . | . | Right | 0.95 | 14 | 14 | Yes | 0 grade | None | |
| 100243 | DROP | Male 74 | 1 | 30NOV2018 | 0.8 | 0.5 | . | . | 16 | 18 | Yes | 0 grade | None | |
| . | . | . | 2 | 06DEC2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 07DEC2018 | . | . | Right | 0.6 | 15 | 16 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 12DEC2018 | . | . | Right | 0.8 | 17 | 17 | Yes | 0 grade | None | |
| . | . | . | 5 | 19DEC2018 | . | . | Right | 0.85 | 17 | 17 | Yes | 0 grade | None | |
| . | . | . | 6 | 04FEB2019 | . | . | Right | 0.85 | 17 | 17 | Yes | 0 grade | None | |
| 100244 | GEL | Female 66 | 1 | 07DEC2018 | 0.3 | 1 | . | . | 10 | 10 | Yes | 0 grade | None | |
| . | . | . | 2 | 13DEC2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 14DEC2018 | . | . | Left | 0.8 | 12 | 12 | Yes | 0 grade | None | |
| . | . | . | 4 | 19DEC2018 | . | . | Left | 1 | 12 | 12 | Yes | 0 grade | None | |
| . | . | . | 5 | 27DEC2018 | . | . | Left | 1 | 12 | 12 | Yes | 0 grade | None | |
| . | . | . | 6 | 08FEB2019 | . | . | Left | 1 | 12 | 12 | Yes | 0 grade | None | |
| 100245 | DROP | Female 69 | 1 | 07DEC2018 | 0.5 | 0.4 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 13DEC2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 14DEC2018 | . | . | Right | 0.8 | 16 | 17 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 19DEC2018 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 27DEC2018 | . | . | Right | 1 | 14 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 08FEB2019 | . | . | Right | 1 | 16 | 16 | Yes | 0 grade | None | |

Listing 6 (20 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

Listing 6 (21 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

Listing 6 (22 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|-------------------|--------------|---------------|-----------|-----|-------|-----------------------|-----------|-----------|-----------|--|-------------------|------------------|
| | | | | Operated eye | | Eye | Value | Left eye | | Right eye | | Performed? | Cellul. grade* | Flare grade** |
| | | | | Left eye | Right eye | | | Left eye | Right eye | Left eye | Right eye | | | |
| 100314 | DROP | Male 67 | 1 | 30NOV2017 | 0 | 0.4 | . | . | 15 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 05DEC2017 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 06DEC2017 | . | . | Right | 0.2 | 16 | 20 | Yes | 0 grade | None | |
| . | . | . | 4 | 13DEC2017 | . | . | Right | 0 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 19DEC2017 | . | . | Right | 0 | 16 | 17 | Yes | 0 grade | None | |
| . | . | . | 6 | 01FEB2018 | . | . | Right | 0 | 16 | 15 | Yes | 0 grade | None | |
| 100315 | GEL | Female 65 | 1 | 30NOV2017 | 0.5 | 0.6 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 05DEC2017 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 06DEC2017 | . | . | Right | 0.1 | 20 | 16 | Yes | 0.5 grade | None | |
| . | . | . | 4 | 13DEC2017 | . | . | Right | 0 | 16 | 18 | Yes | 0 grade | None | |
| . | . | . | 5 | 19DEC2017 | . | . | Right | 0 | 16 | 17 | Yes | 0 grade | None | |
| . | . | . | 6 | 01FEB2018 | . | . | Right | 0 | 16 | 15 | Yes | 0 grade | None | |
| 100316 | DROP | Male 76 | 1 | 30NOV2017 | 0.4 | 0 | . | . | 16 | 15 | Yes | 0 grade | None | |
| . | . | . | 2 | 05DEC2017 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 06DEC2017 | . | . | Left | 0 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 4 | 13DEC2017 | . | . | Left | 0 | 12 | 12 | Yes | 0 grade | None | |
| . | . | . | 5 | 19DEC2017 | . | . | Left | 0 | 18 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 01FEB2018 | . | . | Left | 0 | 15 | 13 | Yes | 0 grade | None | |
| 100317 | GEL | Male 85 | 1 | 30NOV2017 | 0.5 | 0.1 | . | . | 15 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 05DEC2017 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 06DEC2017 | . | . | Right | 0 | 20 | 16 | Yes | 0 grade | None | |
| . | . | . | 4 | 14DEC2017 | . | . | Right | 0.1 | 16 | 13 | Yes | 0 grade | None | |
| . | . | . | 5 | 19DEC2017 | . | . | Right | 0 | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 01FEB2018 | . | . | Right | 0 | 16 | 14 | Yes | 0 grade | None | |
| 100318 | GEL | Female 80 | 1 | 30NOV2017 | 0.1 | 0.4 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 05DEC2017 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 06DEC2017 | . | . | Right | 0.3 | 16 | 18 | Yes | 0 grade | None | |
| . | . | . | 4 | 13DEC2017 | . | . | Right | 0.3 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 19DEC2017 | . | . | Right | 0.3 | 16 | 17 | Yes | 0 grade | None | |
| . | . | . | 6 | 01FEB2018 | . | . | Right | 0.3 | 16 | 16 | Yes | 0 grade | None | |

Listing 6 (23 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|----------------------|--------------|---------------|-----------|-----|-------|-----------------------|-----|-----------|-----|--|-------------------|------------------|
| | | | | Operated eye | | Eye | Value | Left eye | | Right eye | | Performed? | Cellul. grade* | Flare grade** |
| | | | | Left | eye | | | Left | eye | Left | eye | | | |
| 100319 | DROP | Male | 70 | 1 | 29NOV2017 | 0.5 | 0 | . | . | 17 | 15 | Yes | 0 grade | None |
| . | . | . | 2 | 05DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 06DEC2017 | . | . | Left | 0.1 | 15 | 20 | . | 0 grade | None | |
| . | . | . | 4 | 13DEC2017 | . | . | Left | 0.1 | 17 | 16 | . | 0 grade | None | |
| . | . | . | 5 | 19DEC2017 | . | . | Left | 0 | 13 | 15 | . | 0 grade | None | |
| . | . | . | 6 | 01FEB2018 | . | . | Left | 0 | 16 | 15 | . | 0 grade | None | |
| 100320 | DROP | Male | 69 | 1 | 30NOV2017 | 0.4 | 0 | . | . | 18 | 15 | Yes | 0 grade | None |
| . | . | . | 2 | 05DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 06DEC2017 | . | . | Left | 0 | 18 | 16 | . | 0.5 grade | None | |
| . | . | . | 4 | 13DEC2017 | . | . | Left | 0 | 16 | 16 | . | 0 grade | None | |
| . | . | . | 5 | 19DEC2017 | . | . | Left | 0 | 18 | 16 | . | 0 grade | None | |
| . | . | . | 6 | 01JAN2018 | . | . | Left | 0 | 16 | 16 | . | 0 grade | None | |
| 100321 | GEL | Male | 72 | 1 | 06DEC2017 | 0.5 | 0.1 | . | . | 16 | 20 | Yes | 0 grade | None |
| . | . | . | 2 | 11DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 12DEC2017 | . | . | Left | 0 | 16 | 16 | . | 0.5 grade | None | |
| . | . | . | 4 | 27DEC2017 | . | . | Left | 0 | 16 | 16 | . | 0 grade | None | |
| . | . | . | 5 | 27DEC2017 | . | . | Left | 0 | 16 | 16 | . | 0 grade | None | |
| . | . | . | 6 | 05FEB2018 | . | . | Left | 0 | 16 | 16 | . | 0 grade | None | |
| 100322 | GEL | Male | 80 | 1 | 06DEC2017 | 0.6 | 0.1 | . | . | 17 | 17 | Yes | 0 grade | None |
| . | . | . | 2 | 13DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 14DEC2017 | . | . | Right | 0.2 | 16 | 18 | . | 0.5 grade | None | |
| . | . | . | 4 | 19DEC2017 | . | . | Right | 0.1 | 15 | 12 | . | 0 grade | None | |
| . | . | . | 5 | 27DEC2017 | . | . | Right | 0 | 15 | 15 | . | 0 grade | None | |
| . | . | . | 6 | 12FEB2018 | . | . | Right | 0 | 15 | 14 | . | 0 grade | None | |
| 100323 | DROP | Female | 76 | 1 | 06DEC2017 | 0.5 | 0.3 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 13DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 14DEC2017 | . | . | Left | 0.1 | 15 | 14 | . | 0 grade | None | |
| . | . | . | 4 | 19DEC2017 | . | . | Left | 0.1 | 15 | 14 | . | 0 grade | None | |
| . | . | . | 5 | 27DEC2017 | . | . | Left | 0 | 17 | 14 | . | 0 grade | None | |
| . | . | . | 6 | 12FEB2018 | . | . | Left | 0 | 13 | 13 | . | 0 grade | None | |

Listing 6 (24 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|---------|------|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100324 | DROP | Male | 65 | 1 | 13DEC2017 | 0.2 | 0.7 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 18DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 19DEC2017 | . | . | Right | 0 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 4 | 27DEC2017 | . | . | Right | 0 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 02JAN2018 | . | . | Right | 0 | 17 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 16FEB2018 | . | . | Right | 0 | 16 | 16 | Yes | 0 grade | None | |
| 100325 | GEL | Female | 83 | 1 | 13DEC2017 | 0.5 | 0.5 | . | . | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 18DEC2017 | . | . | . | . | . | . | . | . | . | . |
| 100326 | DROP | Male | 81 | 1 | 13DEC2017 | 0.5 | 0 | . | . | 16 | 13 | Yes | 0 grade | None |
| . | . | . | 2 | 18DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 19DEC2017 | . | . | Left | 0 | 18 | 17 | Yes | 0 grade | None | |
| . | . | . | 4 | 27DEC2017 | . | . | Left | 0 | 11 | 11 | Yes | 0 grade | None | |
| . | . | . | 5 | 03JAN2018 | . | . | Left | 0 | 11 | 12 | Yes | 0 grade | None | |
| . | . | . | 6 | 26FEB2018 | . | . | Left | 0 | 17 | 19 | Yes | 0 grade | None | |
| 100327 | GEL | Female | 73 | 1 | 13DEC2017 | 0.4 | 0.8 | . | . | 13 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 18DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 19DEC2017 | . | . | Left | 0 | 20 | 20 | Yes | 0 grade | None | |
| . | . | . | 4 | 27DEC2017 | . | . | Left | 0 | 10 | 10 | Yes | 0 grade | None | |
| . | . | . | 5 | 02JAN2018 | . | . | Left | 0 | 11 | 10 | Yes | 0 grade | None | |
| . | . | . | 6 | 16FEB2018 | . | . | Left | 0 | 10 | 11 | Yes | 0 grade | None | |
| 100328 | DROP | Male | 82 | 1 | 13DEC2017 | 0.3 | 0.4 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 18DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 19DEC2017 | . | . | Right | 0.2 | 19 | 22 | Yes | 0 grade | None | |
| . | . | . | 4 | 27DEC2017 | . | . | Right | 0.1 | 16 | 15 | Yes | 0 grade | None | |
| . | . | . | 5 | 02JAN2018 | . | . | Right | 0.1 | 15 | 14 | Yes | 0 grade | None | |
| . | . | . | 6 | 16FEB2018 | . | . | Right | 0.1 | 14 | 16 | Yes | 0 grade | None | |
| 100329 | GEL | Male | 74 | 1 | 13DEC2017 | 0.3 | 0.2 | . | . | 17 | 15 | Yes | 0 grade | None |
| . | . | . | 2 | 18DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 19DEC2017 | . | . | Left | 0.1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 4 | 27DEC2017 | . | . | Left | 0 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 02JAN2018 | . | . | Left | 0 | 16 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 16FEB2018 | . | . | Left | 0 | 13 | 13 | Yes | 0 grade | None | |

Listing 6 (25 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|-------------------|--------------|---------------|-----------|-----|-------|-----------------------|-----------|-----------|-----------|--|-------------------|------------------|
| | | | | Operated eye | | Eye | Value | Left eye | | Right eye | | Performed? | Cellul. grade* | Flare grade** |
| | | | | Left eye | Right eye | | | Left eye | Right eye | Left eye | Right eye | | | |
| 100330 | DROP | Male | 61 | 1 | 14DEC2017 | 0.5 | 0 | . | . | 17 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 19DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 20DEC2017 | . | . | Left | 0 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 4 | 27DEC2017 | . | . | Left | 0 | 16 | 12 | . | Yes | 0 grade | None |
| . | . | . | 5 | 03JAN2018 | . | . | Left | 0 | 15 | 12 | . | Yes | 0 grade | None |
| . | . | . | 6 | 19FEB2018 | . | . | Left | 0 | 14 | 14 | . | Yes | 0 grade | None |
| 100331 | GEL | Female | 71 | 1 | 14DEC2017 | 0.1 | 0.8 | . | . | 14 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 19DEC2017 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 20DEC2017 | . | . | Right | 0.2 | 16 | 18 | . | Yes | 0 grade | None |
| . | . | . | 4 | 27DEC2017 | . | . | Right | 0.2 | 11 | 13 | . | Yes | 0 grade | None |
| . | . | . | 5 | 03JAN2018 | . | . | Right | 0.1 | 13 | 12 | . | Yes | 0 grade | None |
| . | . | . | 6 | 19FEB2018 | . | . | Right | 0 | 14 | 14 | . | Yes | 0 grade | None |
| 100332 | DROP | Male | 82 | 1 | 05JAN2018 | 0.4 | 0.7 | . | . | 14 | 13 | Yes | 0 grade | None |
| . | . | . | 2 | 12JAN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 13JAN2018 | . | . | Right | 0.2 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 4 | 19JAN2018 | . | . | Right | 0 | 16 | 13 | . | Yes | 0 grade | None |
| . | . | . | 5 | 25JAN2018 | . | . | Right | 0 | 15 | 14 | . | Yes | 0 grade | None |
| . | . | . | 6 | 12MAR2018 | . | . | Right | 0 | 14 | 14 | . | Yes | 0 grade | None |
| 100333 | DROP | Male | 62 | 1 | 19JAN2018 | 0 | 0.5 | . | . | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 25JAN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 26JAN2018 | . | . | Right | 0.1 | 18 | 18 | . | Yes | 0 grade | None |
| . | . | . | 4 | 01FEB2018 | . | . | Right | 0 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 5 | 09FEB2018 | . | . | Right | 0 | 14 | 15 | . | Yes | 0 grade | None |
| . | . | . | 6 | 26MAR2018 | . | . | Right | 0 | 15 | 16 | . | Yes | 0 grade | None |
| 100334 | GEL | Male | 72 | 1 | 19JAN2018 | 0.4 | 0 | . | . | 12 | 12 | Yes | 0 grade | None |
| . | . | . | 2 | 24JAN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 25JAN2018 | . | . | Left | 0.2 | 12 | 12 | . | Yes | 0 grade | None |
| . | . | . | 4 | 01FEB2018 | . | . | Left | 0 | 10 | 10 | . | Yes | 0 grade | None |
| . | . | . | 5 | 08FEB2018 | . | . | Left | 0 | 12 | 12 | . | Yes | 0 grade | None |
| . | . | . | 6 | 26MAR2018 | . | . | Left | 0 | 12 | 12 | . | Yes | 0 grade | None |

Listing 6 (26 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|-------------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|------|---|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100335 | DROP | Female 80 | 1 | 31JAN2018 | 0.3 | 0.5 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 06FEB2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 07FEB2018 | . | . | Right | 0.2 | 18 | 18 | Yes | 0 grade | None | |
| . | . | . | 4 | 12FEB2018 | . | . | Right | 0.1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 20FEB2018 | . | . | Right | 0.1 | 14 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 05APR2018 | . | . | Right | 0.1 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 7 | 19MARCH2018 | . | . | . | . | . | . | Yes | 0 grade | None | |
| 100336 | GEL | Female 82 | 1 | 01MARCH2018 | 0.7 | 0.6 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 06MARCH2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 07MARCH2018 | . | . | Left | 0.3 | 17 | 17 | Yes | 0 grade | None | |
| . | . | . | 4 | 12MARCH2018 | . | . | Left | 0.2 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 20MARCH2018 | . | . | Left | 0.2 | 16 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 02MAY2018 | . | . | Left | 0.2 | 16 | 16 | Yes | 0 grade | None | |
| 100337 | GEL | Male 72 | 1 | 10MARCH2018 | 0 | 0.5 | . | . | 15 | 14 | Yes | 0 grade | None | |
| . | . | . | 2 | 16MARCH2018 | . | . | . | . | . | . | . | . | . | |
| 100338 | DROP | Female 87 | 1 | 15MARCH2018 | 0.2 | 0.6 | . | . | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 2 | 21MARCH2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 22MARCH2018 | . | . | Right | 0.2 | 17 | 17 | Yes | 0 grade | None | |
| . | . | . | 4 | 27MARCH2018 | . | . | Right | 2 | 16 | 14 | Yes | 0 grade | None | |
| . | . | . | 5 | 05APR2018 | . | . | Right | 0.2 | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 21MAY2018 | . | . | Right | 0.1 | 14 | 14 | Yes | 0 grade | None | |
| 100339 | GEL | Male 56 | 1 | 22MARCH2018 | 0 | 0.6 | . | . | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 2 | 28MARCH2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 29MARCH2018 | . | . | Left | 0.1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 4 | 05APR2018 | . | . | Left | 0 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 11APR2018 | . | . | Left | 0 | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 28MAY2018 | . | . | Left | 0 | 14 | 14 | Yes | 0 grade | None | |
| 100340 | DROP | Male 83 | 1 | 05APR2018 | 0.2 | 0.4 | . | . | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 2 | 12APR2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 13APR2018 | . | . | Right | 0.1 | 17 | 17 | Yes | 0 grade | None | |
| . | . | . | 4 | 19APR2018 | . | . | Right | 0.1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 26APR2018 | . | . | Right | 0 | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 12JUN2018 | . | . | Right | 0 | 16 | 16 | Yes | 0 grade | None | |

Listing 6 (27 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|---------|------|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100341 | GEL | Male | 88 | 1 | 05APR2018 | 0.7 | 0.7 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 2 | 12APR2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 13APR2018 | . | . | Left | 0.2 | 14 | 14 | Yes | 0 grade | None |
| . | . | . | . | 4 | 19APR2018 | . | . | Left | 0.1 | 14 | 14 | Yes | 0 grade | None |
| . | . | . | . | 5 | 26APR2018 | . | . | Left | 0.1 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 6 | 12JUL2018 | . | . | Left | 0.1 | 16 | 16 | Yes | 0 grade | None |
| 100342 | DROP | Female | 86 | 1 | 05APR2018 | 0.5 | 0.4 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 2 | 12APR2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 13APR2018 | . | . | Left | 0.2 | 17 | 17 | Yes | 0 grade | None |
| . | . | . | . | 4 | 19APR2018 | . | . | Left | 0 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 5 | 26APR2018 | . | . | Left | 0 | 15 | 15 | Yes | 0 grade | None |
| . | . | . | . | 6 | 12JUN2018 | . | . | Left | 0 | 15 | 15 | Yes | 0 grade | None |
| 100343 | GEL | Male | 74 | 1 | 05APR2018 | 0 | 0.7 | . | . | 12 | 12 | Yes | 0 grade | None |
| . | . | . | . | 2 | 10APR2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 11APR2018 | . | . | Right | 0.1 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 4 | 17APR2018 | . | . | Right | 0.1 | 15 | 15 | Yes | 0 grade | None |
| . | . | . | . | 5 | 24APR2018 | . | . | Right | 0 | 15 | 15 | Yes | 0 grade | None |
| . | . | . | . | 6 | 12JUN2018 | . | . | Right | 0 | 14 | 14 | Yes | 0 grade | None |
| 100344 | DROP | Female | 68 | 1 | 05APR2018 | 0.7 | 0.5 | . | . | 10 | 10 | Yes | 0 grade | None |
| . | . | . | . | 2 | 10APR2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 11APR2018 | . | . | Left | 0.3 | 18 | 18 | Yes | 0 grade | None |
| . | . | . | . | 4 | 17APR2018 | . | . | Left | 0.2 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 5 | 23APR2018 | . | . | Left | 0.2 | 15 | 15 | Yes | 0 grade | None |
| . | . | . | . | 6 | 11JUN2018 | . | . | Left | 0.2 | 16 | 16 | Yes | 0 grade | None |
| 100345 | GEL | Male | 48 | 1 | 05APR2018 | 0.4 | 0 | . | . | 10 | 10 | Yes | 0 grade | None |
| . | . | . | . | 2 | 10APR2018 | . | . | . | . | . | . | . | . | . |
| . | . | . | . | 3 | 11APR2018 | . | . | Left | 0.2 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 4 | 17APR2018 | . | . | Left | 0.1 | 14 | 14 | Yes | 0 grade | None |
| . | . | . | . | 5 | 23APR2018 | . | . | Left | 0.1 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | . | 6 | 11JUN2018 | . | . | Left | 0.1 | 15 | 15 | Yes | 0 grade | None |

Listing 6 (28 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | | |
|-------------|---------------|-------------------|--------------|---------------|-----------|-----|-------|-----------------------|-----------|-----------|-----------|--|-------------------|------------------|------|
| | | | | Operated eye | | Eye | Value | Left eye | | Right eye | | Performed? | Cellul. grade* | Flare grade** | |
| | | | | Left eye | Right eye | | | Left eye | Right eye | Left eye | Right eye | | | | |
| 100346 | DROP | Female 77 | 1 | 06APR2018 | 0.4 | 0.6 | . | . | 14 | 14 | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 12APR2018 | . | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 13APR2018 | . | . | Right | 0.1 | 14 | 14 | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 4 | 19APR2018 | . | . | Right | 0 | 15 | 15 | 15 | 15 | Yes | 0 grade | None |
| . | . | . | 5 | 26APR2018 | . | . | Right | 0 | 16 | 16 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 6 | 12JUN2018 | . | . | Right | 0 | 15 | 15 | 15 | 15 | Yes | 0 grade | None |
| 100347 | GEL | Male 58 | 1 | 12APR2018 | 0.1 | 0.5 | . | . | 14 | 12 | 12 | 12 | Yes | 0 grade | None |
| . | . | . | 2 | 18APR2018 | . | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 19APR2018 | . | . | Right | 0 | 14 | 18 | 18 | 18 | Yes | 0 grade | None |
| . | . | . | 4 | 24APR2018 | . | . | Right | 0 | 14 | 16 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 5 | 02MAY2018 | . | . | Right | 0 | 14 | 15 | 15 | 15 | Yes | 0 grade | None |
| . | . | . | 6 | 18JUN2018 | . | . | Right | 0 | 16 | 16 | 16 | 16 | Yes | 0 grade | None |
| 100348 | GEL | Female 38 | 1 | 19APR2018 | 0.4 | 0.4 | . | . | 16 | 16 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 24APR2018 | . | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 25APR2018 | . | . | Right | 0.1 | 18 | 18 | 18 | 18 | Yes | 0 grade | None |
| . | . | . | 4 | 30APR2018 | . | . | Right | 0 | 16 | 16 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 5 | 08MAY2018 | . | . | Right | 0 | 14 | 14 | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 6 | 25JUN2018 | . | . | Right | 0 | 15 | 15 | 15 | 15 | Yes | 0 grade | None |
| 100349 | DROP | Male 71 | 1 | 18MAY2018 | 0.4 | 0.4 | . | . | 14 | 14 | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 24MAY2018 | . | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 25MAY2018 | . | . | Right | 0.2 | 14 | 14 | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 4 | 30MAY2018 | . | . | Right | 0.1 | 14 | 16 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 5 | 06JUN2018 | . | . | Right | 0.1 | 16 | 16 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 6 | 25JUL2018 | . | . | Right | 0.1 | 16 | 16 | 16 | 16 | Yes | 0 grade | None |
| 100350 | DROP | Female 67 | 1 | 18MAY2018 | 0.4 | 0.7 | . | . | 16 | 16 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 22MAY2018 | . | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 23MAY2018 | . | . | Left | 0.2 | 15 | 16 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 4 | 30MAY2018 | . | . | Left | 0.1 | 15 | 15 | 15 | 15 | Yes | 0 grade | None |
| . | . | . | 5 | 05JUN2018 | . | . | Left | 0 | 16 | 16 | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 6 | 23JUL2018 | . | . | Left | 0 | 15 | 15 | 15 | 15 | Yes | 0 grade | None |

Listing 6 (29 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|---------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|-----------|------|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100351 | GEL | Female | 79 | 1 | 18MAY2018 | 0.5 | 0 | . | . | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 25MAY2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 26MAY2018 | . | . | Left | 0 | 18 | 18 | . | Yes | 0 grade | None |
| . | . | . | 4 | 01JUN2018 | . | . | Left | 0 | 16 | 18 | . | Yes | 0 grade | None |
| . | . | . | 5 | 08JUN2018 | . | . | Left | 0 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 6 | 25JUL2018 | . | . | Left | 0 | 15 | 15 | . | Yes | 0 grade | None |
| 100352 | DROP | Female | 63 | 1 | 23MAY2018 | 0.2 | 0.8 | . | . | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 29MAY2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 30MAY2018 | . | . | Right | 0.2 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 4 | 06JUN2018 | . | . | Right | 0.2 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 5 | 13JUN2018 | . | . | Right | 0.1 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 6 | 30JUL2018 | . | . | Right | 0 | 15 | 15 | . | Yes | 0 grade | None |
| 100353 | GEL | Female | 72 | 1 | 31MAY2018 | 0.5 | 0.2 | . | . | 14 | 15 | Yes | 0 grade | None |
| . | . | . | 2 | 07JUN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 08JUN2018 | . | . | Left | 0.1 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 4 | 14JUN2018 | . | . | Left | 0 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 5 | 21JUN2018 | . | . | Left | 0 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 6 | 31JUL2018 | . | . | Left | 0 | 14 | 14 | . | Yes | 0 grade | None |
| 100354 | GEL | Female | 80 | 1 | 01JUN2018 | 0.5 | 0.5 | . | . | 14 | 14 | Yes | 0 grade | None |
| . | . | . | 2 | 07JUN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 08JUN2018 | . | . | Left | 0.2 | 17 | 17 | . | Yes | 0 grade | None |
| . | . | . | 4 | 14JUN2018 | . | . | Left | 0.2 | 16 | 16 | . | Yes | 0 grade | None |
| . | . | . | 5 | 21JUN2018 | . | . | Left | 0.1 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 6 | 07AUG2018 | . | . | Left | 0.1 | 15 | 15 | . | Yes | 0.5 grade | None |
| . | . | . | 7 | 25JUN2018 | . | . | . | . | . | . | . | Yes | 0 grade | None |
| 100355 | DROP | Female | 80 | 1 | 08JUN2018 | 0.8 | 0.5 | . | . | 16 | 16 | Yes | 0 grade | None |
| . | . | . | 2 | 13JUN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 14JUN2018 | . | . | Left | 0 | 15 | 15 | . | Yes | 0 grade | None |
| . | . | . | 4 | 21JUN2018 | . | . | Left | 0 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 5 | 27JUN2018 | . | . | Left | 0 | 14 | 14 | . | Yes | 0 grade | None |
| . | . | . | 6 | 13AUG2018 | . | . | Left | 0 | 15 | 15 | . | Yes | 0 grade | None |

Listing 6 (30 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|-------------------|--------------|---------------|-----------|--------------|-------|-----------------------|-----------|------------|-------------------|--|-------|---|
| | | | | Left eye | Right eye | Operated eye | | Left eye | Right eye | Performed? | Cellul. grade* | Flare grade** | | |
| | | | | | | Eye | Value | | | | | | | |
| 100356 | GEL | Male 74 | 1 | 12JUN2018 | 0.2 | 0.6 | . | . | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 2 | 18JUN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 19JUN2018 | . | . | Right | 0 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 4 | 26JUN2018 | . | . | Right | 0 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 04JUL2018 | . | . | Right | 0 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 6 | 20AUG2018 | . | . | Right | 0 | 14 | 14 | Yes | 0 grade | None | |
| 200101 | GEL | Female 66 | 1 | 11JAN2018 | 1 | 0.9 | . | . | 19 | 17 | Yes | 0 grade | None | |
| . | . | . | 2 | 16JAN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 17JAN2018 | . | . | Left | 1 | 34 | 16 | Yes | 0.5 grade | None | |
| . | . | . | 4 | 24JAN2018 | . | . | Left | 1.1 | 16 | 17 | Yes | 0.5 grade | None | |
| . | . | . | 5 | 31JAN2018 | . | . | Left | 1 | 17 | 18 | Yes | 0 grade | None | |
| . | . | . | 6 | 19MAR2018 | . | . | Left | 1.1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 7 | 17JAN2018 | . | . | . | . | . | . | Yes | 0.5 grade | None | |
| 200102 | DROP | Female 76 | 1 | 25JAN2018 | 1 | 0.8 | . | . | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 2 | 30JAN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 31JAN2018 | . | . | Right | 0.6 | 12 | 14 | Yes | 1 grade | Faint | |
| . | . | . | 4 | 05FEB2018 | . | . | Right | 0.63 | 11 | 13 | Yes | 0 grade | None | |
| . | . | . | 5 | 13FEB2018 | . | . | Right | 0.9 | 13 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 28MAR2018 | . | . | Right | 1 | 11 | 15 | Yes | 0 grade | None | |
| 200103 | DROP | Male 82 | 1 | 12FEB2018 | 1 | 0.5 | . | . | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 2 | 13FEB2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 14FEB2018 | . | . | Right | 1 | 16 | 12 | Yes | 1 grade | Faint | |
| . | . | . | 4 | 19FEB2018 | . | . | Right | 1 | 15 | 14 | Yes | 0.5 grade | None | |
| . | . | . | 5 | 26FEB2018 | . | . | Right | 0.8 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 16APR2018 | . | . | Left | 1 | 14 | 12 | Yes | 0 grade | None | |
| . | . | . | 7 | 14MARCH2018 | . | . | . | . | . | . | Yes | 0 grade | None | |
| 200104 | GEL | Female 78 | 1 | 03MAY2018 | 0.5 | 0.4 | . | . | 13 | 12 | Yes | 0 grade | None | |
| . | . | . | 2 | 08MAY2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 09MAY2018 | . | . | Right | 0.6 | 15 | 14 | Yes | 0.5 grade | None | |
| . | . | . | 4 | 16MAY2018 | . | . | Right | 1 | 16 | 15 | Yes | 0 grade | None | |
| . | . | . | 5 | 23MAY2018 | . | . | Right | 1 | 17 | 15 | Yes | 0 grade | None | |
| . | . | . | 6 | 06JUN2018 | . | . | Right | 0.9 | 12 | 10 | Yes | 0 grade | None | |

Listing 6 (31 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|-------------------|--------------|---------------|-----------|------|-----------|-----------------------|-----------|-----------|------------|--|-------------------|------------------|
| | | | | Operated eye | | Eye | Value | Left eye | | Right eye | | Performed? | Cellul. grade* | Flare grade** |
| | | | | Left eye | Right eye | | | Left eye | Right eye | Left eye | Right eye | | | |
| 200105 | GEL | Female 65 | 1 | 24MAY2018 | 1 | 1 | . | . | 16 | 15 | Yes | 0 grade | None | |
| . | . | . | 2 | 29MAY2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 30MAY2018 | . | . | Right | 1 | 13 | 15 | Yes | 0 grade | Faint | |
| . | . | . | 4 | 06JUN2018 | . | . | Right | 1.1 | 15 | 12 | Yes | 0 grade | None | |
| . | . | . | 5 | 13JUN2018 | . | . | Right | 1.1 | 19 | 11 | Yes | 0 grade | None | |
| . | . | . | 6 | 23JUN2018 | . | . | Right | 1 | 13 | 12 | Yes | 0 grade | None | |
| 200106 | DROP | Female 75 | 1 | 18JUN2018 | 0.4 | 0.7 | . | . | 20 | 18 | Yes | 0 grade | None | |
| . | . | . | 2 | 26JUN2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 27JUN2018 | . | . | Left | 0.5 | 17 | 15 | Yes | 1 grade | Faint | |
| . | . | . | 4 | 04JUL2018 | . | . | Left | 1 | 15 | 16 | Yes | 0 grade | None | |
| . | . | . | 5 | 11JUL2018 | . | . | Left | 1 | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 22AUG2018 | . | . | (uncode.) | . | . | . | (uncoded). | . | . | |
| 200107 | DROP | Female 54 | 1 | 25JUN2018 | 0.32 | 0.4 | . | . | 19 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 03JUL2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 04JUL2018 | . | . | Left | 0.6 | 17 | 16 | Yes | 1 grade | None | |
| 200108 | GEL | Male 77 | 1 | 29AUG2018 | 0.63 | 0.9 | . | . | 17 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 04SEP2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 05SEP2018 | . | . | Left | 1 | 19 | 14 | Yes | 1 grade | Faint | |
| . | . | . | 4 | 12SEP2018 | . | . | Left | 1 | 16 | 14 | Yes | 0 grade | None | |
| . | . | . | 5 | 20SEP2018 | . | . | Left | 1.1 | 9 | 16 | Yes | 0 grade | None | |
| . | . | . | 6 | 05NOV2018 | . | . | Left | 1 | 11 | 10 | Yes | 0 grade | None | |
| 200109 | GEL | Female 84 | 1 | 29SEP2018 | 0.63 | 0.63 | . | . | 16 | 16 | Yes | 0 grade | None | |
| . | . | . | 2 | 02OCT2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 03OCT2018 | . | . | Right | 0.2 | 16 | 17 | Yes | 0.5 grade | None | |
| . | . | . | 4 | 10OCT2018 | . | . | Right | 0.7 | 15 | 9 | Yes | 0 grade | None | |
| 200110 | DROP | Male 64 | 1 | 05OCT2018 | 0.63 | 0.25 | . | . | 16 | 19 | Yes | 0 grade | None | |
| . | . | . | 2 | 09OCT2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 10OCT2018 | . | . | Right | 0.7 | 16 | 21 | Yes | 0.5 grade | None | |
| . | . | . | 4 | 17OCT2018 | . | . | Right | 0.2 | 17 | 12 | Yes | 0.5 grade | None | |
| . | . | . | 5 | 23OCT2018 | . | . | Right | 0.4 | 12 | 12 | Yes | 0 grade | None | |
| . | . | . | 6 | 05DEC2018 | . | . | Right | 1.1 | 15 | 15 | Yes | 0 grade | None | |

Listing 6 (32 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

Listing 6 (33 of 33): Visual acuity, Intra-ocular pressure and Slit lamp examination during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Visual acuity | | | | Intra-ocular pressure | | | | Slit lamp examination anterior ocular chamber | | |
|-------------|---------------|-------------------|--------------|---------------|-----------|-----|-------|-----------------------|-----------|-----------|-----------|--|-------------------|------------------|
| | | | | Operated eye | | Eye | Value | Left eye | | Right eye | | Performed? | Cellul. grade* | Flare grade** |
| | | | | Left eye | Right eye | | | Left eye | Right eye | Left eye | Right eye | | | |
| 200202 | DROP | Female | 71 | 1 | 13JUN2018 | 1 | . | . | 14 | 12 | Yes | 0 grade | None | |
| . | . | . | 2 | 18JUN2018 | . | . | . | . | . | . | . | . | . | . |
| . | . | . | 3 | 19JUN2018 | . | . | Right | 1.25 | 18 | 18 | Yes | 0.5 grade | None | |
| . | . | . | 4 | 25JUN2018 | . | . | Right | 0.8 | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 5 | 03JUL2018 | . | . | Right | 1.25 | 14 | 14 | Yes | 0 grade | None | |
| . | . | . | 6 | 17AUG2018 | . | . | Right | 1.25 | 12 | 12 | Yes | 0 grade | None | |
| . | . | . | 7 | 06JUL2018 | . | . | . | . | . | . | Yes | 0 grade | None | |
| 200203 | GEL | Male | 66 | 1 | 21JUN2018 | 0.6 | 0.8 | . | 18 | 14 | Yes | 0 grade | None | |
| . | . | . | 2 | 26JUN2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 27JUN2018 | . | . | Left | 0.8 | 15 | 15 | Yes | 1 grade | None | |
| . | . | . | 4 | 02JUL2018 | . | . | Left | 0.63 | 15 | . | Yes | 0.5 grade | None | |
| . | . | . | 5 | 12JUL2018 | . | . | Left | 0.8 | 13 | 13 | Yes | 0 grade | None | |
| . | . | . | 6 | 04SEP2018 | . | . | Left | 1.25 | 14 | 12 | Yes | 0 grade | None | |
| 200204 | GEL | Male | 58 | 1 | 28JUN2018 | 0.5 | 1.25 | . | 15 | 15 | Yes | 0 grade | None | |
| . | . | . | 2 | 03JUL2018 | . | . | . | . | . | . | . | . | . | |
| . | . | . | 3 | 04JUL2018 | . | . | Left | 1 | 14 | 14 | Yes | 1 grade | None | |
| . | . | . | 4 | 10JUL2018 | . | . | Left | 1 | 13 | 13 | Yes | 0 grade | None | |
| . | . | . | 5 | 18JUL2018 | . | . | Left | . | 12 | 13 | Yes | 0 grade | None | |
| . | . | . | 6 | 04SEP2018 | . | . | Left | 1.25 | 12 | 12 | Yes | 0 grade | None | |

SAS program: L03_List_06.sas - SAS dataset name(s): RAND,DEMOGRAPHY,VISUAL_SCREEN,VISUAL_CONTROL,INTRA_PRES,SLIT

* Cellularity grade: 0= <1 cell/field,
0.5= 1-5 cells/field,
1= 6-15 cells/field,
2= 16-25 cells/field,
3= 26-50 cells/field,
4= >50 cells/field

** Flare grade: 0= none
1= faint
2= moderate
3= marked
4= intense

Listing 7 (1 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-----------|------|-----------------|----------------|-----------------|
| | | | | | Performed? | Result | Comment |
| 100101 | DROP | Female | 84 | 1 | 20OCT2017 | Yes | Vitreous Normal |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 26OCT2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 02NOV2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 08NOV2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 27DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| 100102 | GEL | Male | 80 | 1 | 27OCT2017 | Yes | Vitreous Normal |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 01NOV2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 07NOV2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 15NOV2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 29DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (2 of 87): Ophthalmoscopy test during the study

| Visit | | | | | | | | |
|-------------|---------------|---------------|-----------|-----------|------------|----------|----------|--------|
| Sbj Code | Study Drug | Age (year) | No. | Date | Performed? | Result | Comment | |
| 100103 | Female | 70 | 1 | 27OCT2017 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |
| 100104 | GEL | Male | 70 | 1 | 03NOV2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |
| . | . | 3 | 08NOV2017 | Yes | Vitreous | Normal | | |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |
| . | . | 4 | 14NOV2017 | Yes | Vitreous | Normal | | |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |
| . | . | 5 | 22NOV2017 | Yes | Vitreous | Normal | | |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |
| . | . | 6 | 05JAN2018 | Yes | Vitreous | Normal | | |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |

Listing 7 (3 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100105 | DROP | Female | 85 | 1 | 03NOV2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 09NOV2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 15NOV2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 23NOV2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 08JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100106 | GEL | Male | 56 | 1 | 09NOV2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 16NOV2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 22NOV2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 30NOV2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 15JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (4 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-----------|------|-----------------|----------------|-----------------|
| | | | | | Performed? | Result | Comment |
| 100107 | DROP | Female | 82 | 1 | 23NOV2017 | Yes | Vitreous Normal |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 29NOV2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 05DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 13DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 26JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| 100108 | DROP | Female | 73 | 1 | 01DEC2017 | Yes | Vitreous Normal |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 07DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 13DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 21DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 06FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (5 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-----------|-----------|-----------------|-----------------|---------|
| | | | | | Performed? | Result | Comment |
| 100109 | GEL | Female 56 | 1 | 07DEC2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 13DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 19DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 27DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 12FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| 100110 | DROP | Female 75 | 1 | 07DEC2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 14DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 20DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 28DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 12FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (6 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | | | |
| 100111 | DROP | Female 60 | 1 | 07DEC2017 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 14DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 20DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 28DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 12FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100112 | GEL | Male 73 | 1 | 28DEC2017 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 04JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 10JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 17JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 05MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (7 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | |
|-------------|---------------|---------------|--------------|-----------|-----------------|-----------------|---------|
| | | | | | | Result | Comment |
| 100113 | GEL | Female 77 | 1 | 28DEC2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 04JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 10JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 17JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 05MAR2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| 100114 | GEL | Male 64 | 1 | 29DEC2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 04JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 10JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 17JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 05MAR2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (8 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|--------|----------|---------|
| | | | | | | | | |
| 100115 | DROP | Male | 76 | 1 | 29DEC2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 05JAN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 11JAN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 18JAN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 06MAR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| 100116 | GEL | Male | 62 | 1 | 29DEC2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 05JAN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 11JAN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 19JAN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 06MAR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (9 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | | Result | |
| 100117 | DROP | Female 51 | 1 | 04JAN2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 11JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 17JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 23JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 12MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100118 | DROP | Female 78 | 1 | 11JAN2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 18JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 24JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 31JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 19MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (10 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100119 | DROP | Female | 72 | 1 | 19JAN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 25JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 31JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 08FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 26MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Abnormal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100120 | GEL | Male | 79 | 1 | 19JAN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 25JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 31JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 07FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 26MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (11 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|-----|----------|---------|
| | | | | | | | | |
| 100121 | GEL | Male | 80 | 1 | 19JAN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 25JAN2018 | Yes | . | Choroid | Normal |
| . | . | . | . | . | . | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 31JAN2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 07FEB2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 26MAR2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| 100122 | DROP | Female | 76 | 1 | 19JAN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 26JAN2018 | Yes | . | Choroid | Normal |
| . | . | . | . | . | . | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 01FEB2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 08FEB2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 27MAR2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (12 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | | Result | |
| 100123 | DROP | Female 76 | 1 | 19JAN2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 26JAN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 01FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 08FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 27MAR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100124 | GEL | Female 71 | 1 | 26JAN2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 02FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 08FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 16FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 03APR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (13 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | | | |
| 100125 | GEL | Female 62 | 1 | 26JAN2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 02FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 08FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 16FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 03APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100126 | GEL | Female 85 | 1 | 02FEB2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 08FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 14FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 21FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 09APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (14 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | Result | | |
| 100127 | GEL | Female 68 | 1 | 02FEB2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 09FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 15FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 24FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | 6 | 10APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100128 | DROP | Male 80 | 1 | 02FEB2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 09FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 15FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 24FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 10APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (15 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|--------|----------|---------|
| | | | | | | Result | | |
| 100129 | DROP | Female | 78 | 1 | 02FEB2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 09FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 15FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 23FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 10APR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| 100130 | GEL | Male | 66 | 1 | 16FEB2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 22FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 28FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 07MAR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 23APR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (16 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|-------------|--------|----------|----------|
| | | | | | | Result | | |
| 100131 | DROP | Female | 77 | 1 | 16FEB2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 22FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 28FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 07MAR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 23APR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Abnormal |
| 100132 | DROP | Male | 69 | 1 | 02MARCH2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 08MARCH2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 14MARCH2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 21MARCH2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 08MAY2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (17 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100133 | GEL | Male | 74 | 1 | 02MAR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 08MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 14MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 21MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 08MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100134 | DROP | Female | 66 | 1 | 02MAR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 08MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 14MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 21MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 08MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (18 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100135 | GEL | Male | 69 | 1 | 09MAR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 16MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 22MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 29MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 15MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100136 | GEL | Female | 90 | 1 | 30MAR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 06APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 12APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 20APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 06JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (19 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | Result | | |
| 100137 | DROP | Female 62 | 1 | 13APR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 20APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 26APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 04MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 19JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100138 | GEL | Male 63 | 1 | 13APR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 20APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 26APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 04MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 19JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (20 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|--------|----------|---------|
| | | | | | | Result | | |
| 100139 | DROP | Female | 71 | 1 | 20APR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 27APR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 03MAY2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 11MAY2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 26JUN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| 100140 | GEL | Male | 81 | 1 | 27APR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 03MAY2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 09MAY2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 17MAY2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 02JUL2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (21 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | | | |
| 100141 | DROP | Female 74 | 1 | 27APR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 03MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 10MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 16MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 02JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100142 | GEL | Female 77 | 1 | 11MAY2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 17MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 23MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 31MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 16JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (22 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|----------|---------|
| | | | | | | | | |
| 100143 | GEL | Male | 74 | 1 | 15JUN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 21JUN2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 27JUN2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 04JUL2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 20AUG2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| 100144 | DROP | Female | 89 | 1 | 22JUN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 28JUN2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 04JUL2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 12JUL2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 27AUG2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (23 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|----------|---------|
| | | | | | | | | |
| 100145 | GEL | Male | 81 | 1 | 29JUN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 05JUL2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 11JUL2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 18JUL2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 04SEP2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| 100146 | GEL | Male | 71 | 1 | 17AUG2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 22AUG2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 29AUG2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 06SEP2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 22OCT2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (24 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | Result | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|----------|---------|
| | | | | | | | | |
| 100147 | DROP | Male | 48 | 1 | 24AUG2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 3 | 29AUG2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 20SEP2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| 100148 | DROP | Female | 83 | 1 | 24AUG2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 3 | 31AUG2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 06SEP2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 13SEP2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 29OCT2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (25 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | | | |
| 100149 | DROP | Female 71 | 1 | 24AUG2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 31AUG2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 06SEP2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 15SEP2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 29OCT2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100150 | GEL | Female 77 | 1 | 31AUG2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 06SEP2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 12SEP2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 21SEP2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 05NOV2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (26 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | Result | | |
| 100151 | DROP | Female 67 | 1 | 28SEP2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 05OCT2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 12OCT2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 20OCT2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 04DEC2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100152 | GEL | Female 78 | 1 | 28SEP2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 05OCT2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 12OCT2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 20OCT2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (27 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit | | Performed? | Result | Comment |
|-------------|---------------|---------------|-----------|-----------|------------|-----------------|---------|
| | | | No. | Date | | | |
| 100153 | DROP | Female 81 | 1 | 12OCT2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 18OCT2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 24OCT2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 29OCT2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 18DEC2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| 100154 | GEL | Female 68 | 1 | 12OCT2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 19OCT2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 26OCT2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 02NOV2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 18DEC2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (28 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | | | |
| 100155 | DROP | Female 79 | 1 | 12OCT2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 19OCT2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 26OCT2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 02NOV2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 18DEC2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100156 | GEL | Female 69 | 1 | 12OCT2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 19OCT2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 26OCT2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 02NOV2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 18DEC2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (29 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-----------|-----------|-----------------|-----------------|---------|
| | | | | | Performed? | Result | Comment |
| 100201 | GEL | Female 80 | 1 | 01DEC2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Abnormal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 09DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Abnormal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 13DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Abnormal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 22DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Abnormal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 08FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Abnormal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| 100202 | DROP | Female 70 | 1 | 01DEC2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 09DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 14DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 20DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 08FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (30 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100203 | DROP | Female | 76 | 1 | 07DEC2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 15DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 20DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 28DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 15FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100204 | GEL | Male | 71 | 1 | 07DEC2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 15DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 20DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 28DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 15FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (31 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100205 | GEL | Male | 75 | 1 | 14DEC2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 09FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 14FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 21FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 09APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100206 | DROP | Female | 81 | 1 | 05JAN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 12JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 18JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 24JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 14MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (32 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|----------|---------|
| | | | | | | Result | | |
| 100207 | DROP | Female 65 | 1 | 05JAN2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Abnormal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Abnormal | . |
| . | . | 3 | 12JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Abnormal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Abnormal | . |
| . | . | 4 | 18JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Abnormal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Abnormal | . |
| . | . | 5 | 24JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Abnormal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Abnormal | . |
| . | . | 6 | 14MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100208 | GEL | Female 79 | 1 | 05JAN2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 12JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 18JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 31JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 14MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (33 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-----------|-----------|-----------------|-----------------|---------|
| | | | | | Performed? | Result | Comment |
| 100209 | GEL | Female 77 | 1 | 12JAN2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| 100210 | DROP | Female 70 | 1 | 12JAN2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 19JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 24JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 31JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 22MAR2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (34 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100211 | GEL | Male | 67 | 1 | 12JAN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 19JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 24JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 31JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 22MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100212 | DROP | Female | 82 | 1 | 12JAN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 19JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 24JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 31JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 22MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (35 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-----|-----------|------------|--------------------|-------------------|
| | | | | | Performed? | Result | Comment |
| 100213 | DROP | Female | 81 | 1 | 25JAN2018 | Yes | Vitreous Normal . |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Abnormal . | |
| . | . | . | 3 | 02FEB2018 | Yes | Vitreous Normal . | |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Abnormal . | |
| . | . | . | 4 | 07FEB2018 | Yes | Vitreous Normal . | |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Abnormal . | |
| . | . | . | 5 | 16FEB2018 | Yes | Vitreous Normal . | |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Abnormal . | |
| . | . | . | 6 | 04APR2018 | Yes | Vitreous Normal . | |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Abnormal . | |
| 100214 | DROP | Female | 77 | 1 | 05FEB2018 | Yes | Vitreous Normal . |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Normal . | |
| . | . | . | 3 | 09FEB2018 | Yes | Vitreous Normal . | |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Normal . | |
| . | . | . | 4 | 14FEB2018 | Yes | Vitreous Normal . | |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Normal . | |
| . | . | . | 5 | 21FEB2018 | Yes | Vitreous Normal . | |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Normal . | |
| . | . | . | 6 | 09APR2018 | Yes | Vitreous Normal . | |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Normal . | |

Listing 7 (36 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit | | | | |
|-------------|---------------|---------------|-----------|-----------|------------|----------|---------|
| | | | No. | Date | Performed? | Result | Comment |
| 100215 | GEL | Female 83 | 1 | 05FEB2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 09FEB2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 14FEB2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 21FEB2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 09APR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | Choroid | Normal |
| 100216 | GEL | Female 74 | 1 | 09FEB2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 16FEB2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 21FEB2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 28FEB2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 16APR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | Choroid | Normal |

Listing 7 (37 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | Result | | |
| 100217 | DROP | Female | 72 | 1 | 02MAR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 09MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 14MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 21MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 08MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| 100218 | DROP | Male | 72 | 1 | 02MAR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 09MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 14MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 21MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 08MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (38 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|----------|
| | | | | | | | | |
| 100219 | GEL | Female | 83 | 1 | 09MAR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Abnormal |
| . | . | 3 | 16MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 21MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 28MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 16MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100220 | GEL | Male | 64 | 1 | 09MAR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 16MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 21MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 28MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 16MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (39 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | | Result | |
| 100221 | GEL | Female 76 | 1 | 30MAR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 06APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 11APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 20APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 01JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100222 | DROP | Female 76 | 1 | 05APR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 13APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 18APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 26APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 14JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (40 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100223 | DROP | Male | 61 | 1 | 05APR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 13APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 18APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 26APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 14JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100224 | GEL | Female | 75 | 1 | 20APR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 27APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 02MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 09MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 27JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (41 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | Result | | |
| 100225 | DROP | Female 79 | 1 | 20APR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 27APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 02MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 09MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 27JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100226 | GEL | Female 74 | 1 | 20APR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 27APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 02MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 09MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 27JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (42 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | Result | | |
| 100227 | DROP | Female 68 | 1 | 27APR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 04MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 09MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 16MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 04JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100228 | GEL | Female 68 | 1 | 27APR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 04MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 09MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (43 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | | | |
| 100229 | GEL | Female 70 | 1 | 04MAY2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 11MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 16MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 23MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 10JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100230 | GEL | Female 63 | 1 | 04MAY2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 11MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 16MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 23MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 11JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (44 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | Result | | |
| 100231 | DROP | Female 74 | 1 | 04MAY2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 11MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 16MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 23MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 06JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100232 | DROP | Female 73 | 1 | 04MAY2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 11MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 16MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 23MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 06JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | 7 | . | . | . | Choroid | Normal | . |

Listing 7 (45 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | | | |
| 100233 | GEL | Female 72 | 1 | 18MAY2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 25MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 30MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 06JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 20JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100234 | GEL | Female 73 | 1 | 18MAY2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 25MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 30MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 06JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 20JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (46 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100235 | DROP | Male | 64 | 1 | 28MAY2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 01JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 06JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 13JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 01AUG2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100236 | DROP | Female | 70 | 1 | 28MAY2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 01JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 06JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 13JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 01AUG2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (47 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | Result | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|-----|----------|----------|
| | | | | | | | | |
| 100237 | DROP | Male | 73 | 1 | 01JUN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Abnormal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 08JUN2018 | Yes | . | Choroid | Normal |
| . | . | . | . | . | . | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Abnormal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 13JUN2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Abnormal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 20JUN2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Abnormal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 06AUG2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Abnormal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| 100238 | GEL | Male | 78 | 1 | 01JUN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 08JUN2018 | Yes | . | Choroid | Normal |
| . | . | . | . | . | . | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 13JUN2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 20JUN2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 06AUG2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (48 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | Result | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|--|-----------------|---------|
| | | | | | | | | |
| 100239 | DROP | Female 80 | 1 | 08JUN2018 | Yes | | Vitreous Normal | . |
| . | . | . | . | . | . | | Retina Normal | . |
| . | . | . | . | . | . | | Macula Normal | . |
| . | . | . | . | . | . | | Choroid Normal | . |
| . | . | 3 | 15JUN2018 | Yes | | | Vitreous Normal | . |
| . | . | . | . | . | . | | Retina Normal | . |
| . | . | . | . | . | . | | Macula Normal | . |
| . | . | . | . | . | . | | Choroid Normal | . |
| . | . | 4 | 20JUN2018 | Yes | | | Vitreous Normal | . |
| . | . | . | . | . | . | | Retina Normal | . |
| . | . | . | . | . | . | | Macula Normal | . |
| . | . | . | . | . | . | | Choroid Normal | . |
| . | . | 5 | 27JUN2018 | Yes | | | Vitreous Normal | . |
| . | . | . | . | . | . | | Retina Normal | . |
| . | . | . | . | . | . | | Macula Normal | . |
| . | . | . | . | . | . | | Choroid Normal | . |
| . | . | 6 | 14AUG2018 | Yes | | | Vitreous Normal | . |
| . | . | . | . | . | . | | Retina Normal | . |
| . | . | . | . | . | . | | Macula Normal | . |
| . | . | . | . | . | . | | Choroid Normal | . |
| 100240 | | Female 72 | 1 | 06JUL2018 | Yes | | Vitreous Normal | . |
| . | . | . | . | . | . | | Retina Normal | . |
| . | . | . | . | . | . | | Macula Normal | . |
| . | . | . | . | . | . | | Choroid Normal | . |

Listing 7 (49 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-----------|-----------|-----------------|-----------------|---------|
| | | | | | Performed? | Result | Comment |
| 100241 | GEL | Female 74 | 1 | 23OCT2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 26OCT2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 31OCT2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 07NOV2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 24DEC2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| 100242 | GEL | Female 67 | 1 | 31OCT2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 09NOV2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 14NOV2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 22NOV2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 12JAN2019 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (50 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | Result | |
| 100243 | DROP | Male | 74 | 1 | 30NOV2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 07DEC2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 12DEC2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 19DEC2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 04FEB2019 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100244 | GEL | Female | 66 | 1 | 07DEC2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 14DEC2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 19DEC2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 27DEC2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 08FEB2019 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (51 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-----------|-----------|-----------------|-----------------|---------|
| | | | | | Performed? | Result | Comment |
| 100245 | DROP | Female 69 | 1 | 07DEC2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 14DEC2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 19DEC2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 27DEC2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 08FEB2019 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| 100301 | GEL | Female 68 | 1 | 13OCT2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 20OCT2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 25OCT2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 03NOV2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 20DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 7 | 13DEC2017 | . | . | . | . |

Listing 7 (52 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|----------|---------|
| | | | | | | | | |
| 100302 | GEL | Male | 61 | 1 | 26OCT2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 03NOV2017 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 09NOV2017 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 17NOV2017 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 05JAN2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 7 | 29NOV2017 | . | . | . | . |
| 100303 | DROP | Female | 73 | 1 | 26OCT2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 03NOV2017 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 09NOV2017 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 17NOV2017 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 05JAN2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (53 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100304 | DROP | Male | 58 | 1 | 10NOV2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 17NOV2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 23NOV2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 30NOV2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 16JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100305 | DROP | Female | 85 | 1 | 10NOV2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 17NOV2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 23NOV2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 30NOV2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 16JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (54 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | Result | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|--|-----------------|---------|
| | | | | | | | | |
| 100306 | DROP | Female 84 | 1 | 16NOV2017 | Yes | | Vitreous Normal | . |
| . | . | . | . | . | . | | Retina Abnormal | . |
| . | . | . | . | . | . | | Macula Normal | . |
| . | . | . | . | . | . | | Choroid Normal | . |
| 100307 | GEL | Female 73 | 1 | 24NOV2017 | Yes | | Vitreous Normal | . |
| . | . | . | . | . | . | | Retina Normal | . |
| . | . | . | . | . | . | | Macula Normal | . |
| . | . | . | . | . | . | | Choroid Normal | . |
| . | . | . | 3 | 30NOV2017 | Yes | | Vitreous Normal | . |
| . | . | . | . | . | . | | Retina Normal | . |
| . | . | . | . | . | . | | Macula Normal | . |
| . | . | . | . | . | . | | Choroid Normal | . |
| . | . | . | 4 | 06DEC2017 | Yes | | Vitreous Normal | . |
| . | . | . | . | . | . | | Retina Normal | . |
| . | . | . | . | . | . | | Macula Normal | . |
| . | . | . | . | . | . | | Choroid Normal | . |
| . | . | . | 5 | 14DEC2017 | Yes | | Vitreous Normal | . |
| . | . | . | . | . | . | | Retina Normal | . |
| . | . | . | . | . | . | | Macula Normal | . |
| . | . | . | . | . | . | | Choroid Normal | . |
| . | . | . | 6 | 29JAN2018 | Yes | | Vitreous Normal | . |
| . | . | . | . | . | . | | Retina Normal | . |
| . | . | . | . | . | . | | Macula Normal | . |
| . | . | . | . | . | . | | Choroid Normal | . |
| 100308 | GEL | Female 85 | 1 | 24NOV2017 | Yes | | Vitreous Normal | . |
| . | . | . | . | . | . | | Retina Normal | . |
| . | . | . | . | . | . | | Macula Normal | . |
| . | . | . | . | . | . | | Choroid Normal | . |

Listing 7 (55 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-----------|-----------|-----------------|------------------|---------|
| | | | | | Performed? | Result | Comment |
| 100309 | DROP | Female 61 | 1 | 24NOV2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 30NOV2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 06DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 14DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 29JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Abnormal | . |
| 100310 | GEL | Female 73 | 1 | 24NOV2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 01DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 06DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 14DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 29JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (56 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-----------|------|-----------------|----------------|-----------------|
| | | | | | Performed? | Result | Comment |
| 100311 | GEL | Female | 83 | 1 | 29NOV2017 | Yes | Vitreous Normal |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 06DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 13DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 19DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 01FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| 100312 | DROP | Female | 71 | 1 | 29NOV2017 | Yes | Vitreous Normal |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 06DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 13DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 19DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 01FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (57 of 87): Ophthalmoscopy test during the study

| Visit | | | | | | | | |
|-------------|---------------|----------------------|-----|-----------|------------|----------|---------|---|
| Sbj Code | Study Drug | Age Sex (year) | No. | Date | Performed? | Result | Comment | |
| 100313 | GEL | Male 71 | 1 | 29NOV2017 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100314 | DROP | Male 67 | 1 | 30NOV2017 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | . | 3 | 06DEC2017 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | . | 4 | 13DEC2017 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | . | 5 | 19DEC2017 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | . | 6 | 01FEB2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (58 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit | | Performed? | Result | Comment |
|-------------|---------------|---------------|-----------|-----------|------------|-----------------|---------|
| | | | No. | Date | | | |
| 100315 | GEL | Female 65 | 1 | 30NOV2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 06DEC2017 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 13DEC2017 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 19DEC2017 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 01FEB2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| 100316 | DROP | Male 76 | 1 | 30NOV2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 06DEC2017 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 13DEC2017 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 19DEC2017 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 01FEB2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (59 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit | | Performed? | Result | Comment |
|-------------|---------------|---------------|-------|-----------|------------|-----------------|---------|
| | | | No. | Date | | | |
| 100317 | GEL | Male 85 | 1 | 30NOV2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | 3 | 06DEC2017 | Yes | Choroid Normal | . |
| . | . | . | . | . | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | . | 4 | 14DEC2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | . | 5 | 19DEC2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | . | 6 | 01FEB2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| 100318 | GEL | Female 80 | 1 | 30NOV2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | 3 | 06DEC2017 | Yes | Choroid Normal | . |
| . | . | . | . | . | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | . | 4 | 13DEC2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | . | 5 | 19DEC2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | . | 6 | 01FEB2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (60 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|---------|----------|---------|
| | | | | | | Result | | |
| 100319 | DROP | Male | 70 | 1 | 29NOV2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 06DEC2017 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | Retina | Normal | . | . |
| . | . | . | . | . | Macula | Normal | . | . |
| . | . | . | . | . | Choroid | Normal | . | . |
| . | . | 4 | 13DEC2017 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | Retina | Normal | . | . |
| . | . | . | . | . | Macula | Normal | . | . |
| . | . | . | . | . | Choroid | Normal | . | . |
| . | . | 5 | 19DEC2017 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | Retina | Normal | . | . |
| . | . | . | . | . | Macula | Normal | . | . |
| . | . | . | . | . | Choroid | Normal | . | . |
| . | . | 6 | 01FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | Retina | Normal | . | . |
| . | . | . | . | . | Macula | Normal | . | . |
| . | . | . | . | . | Choroid | Normal | . | . |
| 100320 | DROP | Male | 69 | 1 | 30NOV2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 06DEC2017 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | Retina | Normal | . | . |
| . | . | . | . | . | Macula | Normal | . | . |
| . | . | . | . | . | Choroid | Normal | . | . |
| . | . | 4 | 13DEC2017 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | Retina | Normal | . | . |
| . | . | . | . | . | Macula | Normal | . | . |
| . | . | . | . | . | Choroid | Normal | . | . |
| . | . | 5 | 19DEC2017 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | Retina | Normal | . | . |
| . | . | . | . | . | Macula | Normal | . | . |
| . | . | . | . | . | Choroid | Normal | . | . |
| . | . | 6 | 01JAN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | Retina | Normal | . | . |
| . | . | . | . | . | Macula | Normal | . | . |
| . | . | . | . | . | Choroid | Normal | . | . |

Listing 7 (61 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100321 | GEL | Male | 72 | 1 | 06DEC2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 12DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 27DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 27DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 05FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100322 | GEL | Male | 80 | 1 | 06DEC2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 14DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 19DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 27DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 12FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (62 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-----------|------|-----------------|----------------|-----------------|
| | | | | | Performed? | Result | Comment |
| 100323 | DROP | Female | 76 | 1 | 06DEC2017 | Yes | Vitreous Normal |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 14DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 19DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 27DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 12FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| 100324 | DROP | Male | 65 | 1 | 13DEC2017 | Yes | Vitreous Normal |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 19DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 27DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 02JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 16FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (63 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | |
|-------------|---------------|---------------|--------------|-----------|-----------------|-----------------|---|
| | | | | | Result | Comment | |
| 100325 | GEL | Female 83 | 1 | 13DEC2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| 100326 | DROP | Male 81 | 1 | 13DEC2017 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 19DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 27DEC2017 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 03JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 26FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (64 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|--------|----------|---------|
| | | | | | | Result | | |
| 100327 | GEL | Female | 73 | 1 | 13DEC2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 19DEC2017 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 27DEC2017 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 02JAN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 16FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| 100328 | DROP | Male | 82 | 1 | 13DEC2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 19DEC2017 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 27DEC2017 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 02JAN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 16FEB2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (65 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100329 | GEL | Male | 74 | 1 | 13DEC2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 19DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 27DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 02JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 16FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100330 | DROP | Male | 61 | 1 | 14DEC2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 20DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 27DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 03JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 19FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (66 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100331 | GEL | Female | 71 | 1 | 14DEC2017 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 20DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 27DEC2017 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 03JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 19FEB2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100332 | DROP | Male | 82 | 1 | 05JAN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 13JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 19JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 25JAN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 12MAR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (67 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|----------|---------|
| | | | | | | | | |
| 100333 | DROP | Male | 62 | 1 | 19JAN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 26JAN2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 01FEB2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 09FEB2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 26MAR2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| 100334 | GEL | Male | 72 | 1 | 19JAN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 25JAN2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 01FEB2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 08FEB2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 26MAR2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (68 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-------------|-------------|-----------------|-----------------|---------|
| | | | | | Performed? | Result | Comment |
| 100335 | DROP | Female 80 | 1 | 31JAN2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 07FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 12FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 20FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 05APR2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 7 | 19MAR2018 | . | . | . | . |
| 100336 | GEL | Female 82 | 1 | 01MARCH2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 07MARCH2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 12MARCH2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 20MARCH2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 02MAY2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (69 of 87): Ophthalmoscopy test during the study

| Visit | | | | | | | | |
|-------------|---------------|----------------------|-----|-----------|------------|----------|---------|---|
| Sbj Code | Study Drug | Age Sex (year) | No. | Date | Performed? | Result | Comment | |
| 100337 | GEL | Male 72 | 1 | 10MAR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100338 | DROP | Female 87 | 1 | 15MAR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | . | 3 | 22MAR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | . | 4 | 27MAR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | . | 5 | 05APR2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | . | 6 | 21MAY2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (70 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | Result | |
| 100339 | GEL | Male | 56 | 1 | 22MAR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 29MAR2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |
| . | . | 4 | 05APR2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |
| . | . | 5 | 11APR2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |
| . | . | 6 | 28MAY2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |
| 100340 | DROP | Male | 83 | 1 | 05APR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |
| . | . | 3 | 13APR2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |
| . | . | 4 | 19APR2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |
| . | . | 5 | 26APR2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |
| . | . | 6 | 12JUN2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | Retina | Normal | |
| . | . | . | . | . | . | Macula | Normal | |
| . | . | . | . | . | . | Choroid | Normal | |

Listing 7 (71 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | Result | |
| 100341 | GEL | Male | 88 | 1 | 05APR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 13APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 19APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 26APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 12JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100342 | DROP | Female | 86 | 1 | 05APR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 13APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 19APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 26APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 12JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (72 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100343 | GEL | Male | 74 | 1 | 05APR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 11APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 17APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 24APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 12JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100344 | DROP | Female | 68 | 1 | 05APR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 11APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 17APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 23APR2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 11JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (73 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|--------|----------|---------|
| | | | | | | Result | | |
| 100345 | GEL | Male | 48 | 1 | 05APR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 11APR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 17APR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 23APR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 11JUN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| 100346 | DROP | Female | 77 | 1 | 06APR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 13APR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 19APR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 26APR2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 12JUN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (74 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|----------|---------|
| | | | | | | | | |
| 100347 | GEL | Male | 58 | 1 | 12APR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 19APR2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 24APR2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 02MAY2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 18JUN2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| 100348 | GEL | Female | 38 | 1 | 19APR2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 25APR2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 30APR2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 08MAY2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 25JUN2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (75 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|---------|
| | | | | | | | | |
| 100349 | DROP | Male | 71 | 1 | 18MAY2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 25MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 30MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 06JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 25JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100350 | DROP | Female | 67 | 1 | 18MAY2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 23MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 30MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 05JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 23JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (76 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | | | |
| 100351 | GEL | Female 79 | 1 | 18MAY2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 26MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 01JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 08JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 25JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100352 | DROP | Female 63 | 1 | 23MAY2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 30MAY2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 06JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 13JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 30JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |

Listing 7 (77 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|--------|---------|
| | | | | | | Result | | |
| 100353 | GEL | Female 72 | 1 | 31MAY2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 08JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 14JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 21JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 31JUL2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| 100354 | GEL | Female 80 | 1 | 01JUN2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 3 | 08JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 4 | 14JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 5 | 21JUN2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 6 | 07AUG2018 | Yes | . | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | Normal | . |
| . | . | . | . | . | . | Macula | Normal | . |
| . | . | . | . | . | . | Choroid | Normal | . |
| . | . | 7 | 25JUN2018 | . | . | . | . | . |

Listing 7 (78 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|--------|----------|---------|
| | | | | | | Result | | |
| 100355 | DROP | Female | 80 | 1 | 08JUN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 14JUN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 21JUN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 27JUN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 13AUG2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| 100356 | GEL | Male | 74 | 1 | 12JUN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 19JUN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 26JUN2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 04JUL2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 20AUG2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (79 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-----------|-----------|-----------------|------------------|---------|
| | | | | | Performed? | Result | Comment |
| 200101 | GEL | Female 66 | 1 | 11JAN2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 17JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 24JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 31JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 19MAR2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Not done | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Not done | . |
| . | . | 7 | 17JAN2018 | . | . | . | . |
| 200102 | DROP | Female 76 | 1 | 25JAN2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 31JAN2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 05FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 13FEB2018 | Yes | Vitreous Normal | . | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Not done | . |
| . | . | 6 | 28MAR2018 | No | Vitreous . | . | . |
| . | . | . | . | . | . | Retina . | . |
| . | . | . | . | . | . | Macula . | . |
| . | . | . | . | . | . | Choroid . | . |

Listing 7 (80 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|--------|----------|----------|
| | | | | | | Result | | |
| 200103 | DROP | Male | 82 | 1 | 12FEB2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 14FEB2018 | Yes | . | Choroid | Not done |
| . | . | . | . | . | . | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Not done |
| . | . | . | 4 | 19FEB2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 5 | 26FEB2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 16APR2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 7 | 14MAR2018 | . | . | . | . |
| 200104 | GEL | Female | 78 | 1 | 03MAY2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 09MAY2018 | Yes | . | Choroid | Normal |
| . | . | . | . | . | . | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Not done |
| . | . | . | 4 | 16MAY2018 | No | . | Vitreous | . |
| . | . | . | . | . | . | . | Retina | . |
| . | . | . | . | . | . | . | Macula | . |
| . | . | . | . | . | . | . | Choroid | . |
| . | . | . | 5 | 23MAY2018 | No | . | Vitreous | . |
| . | . | . | . | . | . | . | Retina | . |
| . | . | . | . | . | . | . | Macula | . |
| . | . | . | . | . | . | . | Choroid | . |
| . | . | . | 6 | 06JUN2018 | Yes | . | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (81 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-----------|-----------|------------|-----------------|---------|
| | | | | | Performed? | Result | Comment |
| 200105 | GEL | Female 65 | 1 | 24MAY2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 30MAY2018 | No | Vitreous | . | . |
| . | . | . | . | . | . | Retina | . |
| . | . | . | . | . | . | Macula | . |
| . | . | . | . | . | . | Choroid | . |
| . | . | 4 | 06JUN2018 | No | Vitreous | . | . |
| . | . | . | . | . | . | Retina | . |
| . | . | . | . | . | . | Macula | . |
| . | . | . | . | . | . | Choroid | . |
| . | . | 5 | 13JUN2018 | No | Vitreous | . | . |
| . | . | . | . | . | . | Retina | . |
| . | . | . | . | . | . | Macula | . |
| . | . | . | . | . | . | Choroid | . |
| . | . | 6 | 23JUN2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina | . |
| . | . | . | . | . | . | Macula | . |
| . | . | . | . | . | . | Choroid | Normal |
| 200106 | DROP | Female 75 | 1 | 18JUN2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 27JUN2018 | Yes | Vitreous | Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 04JUL2018 | No | Vitreous | . | . |
| . | . | . | . | . | . | Retina | . |
| . | . | . | . | . | . | Macula | . |
| . | . | . | . | . | . | Choroid | . |
| . | . | 5 | 11JUL2018 | No | Vitreous | . | . |
| . | . | . | . | . | . | Retina | . |
| . | . | . | . | . | . | Macula | . |
| . | . | . | . | . | . | Choroid | . |
| . | . | 6 | 22AUG2018 | (uncoded) | Vitreous | . | . |
| . | . | . | . | . | . | Retina | . |
| . | . | . | . | . | . | Macula | . |
| . | . | . | . | . | . | Choroid | . |

Listing 7 (82 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit | | Performed? | Result | Comment |
|-------------|---------------|---------------|-----------|-----------|------------|-----------------|---------|
| | | | No. | Date | | | |
| 200107 | DROP | Female 54 | 1 | 25JUN2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 04JUL2018 | No | . | Vitreous . | . |
| . | . | . | . | . | . | Retina . | . |
| . | . | . | . | . | . | Macula . | . |
| . | . | . | . | . | . | Choroid . | . |
| 200108 | GEL | Male 77 | 1 | 29AUG2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 05SEP2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 12SEP2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 5 | 20SEP2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 6 | 05NOV2018 | No | . | Vitreous . | . |
| . | . | . | . | . | . | Retina . | . |
| . | . | . | . | . | . | Macula . | . |
| . | . | . | . | . | . | Choroid . | . |
| 200109 | GEL | Female 84 | 1 | 29SEP2018 | Yes | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 3 | 03OCT2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |
| . | . | 4 | 10OCT2018 | Yes | . | Vitreous Normal | . |
| . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | Choroid Normal | . |

Listing 7 (83 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|--------|----------|---------|
| | | | | | | Result | | |
| 200110 | DROP | Male | 64 | 1 | 05OCT2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 10OCT2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 17OCT2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 23OCT2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 05DEC2018 | No | Vitreous | . | . | . |
| . | . | . | . | . | . | . | Retina | . |
| . | . | . | . | . | . | . | Macula | . |
| . | . | . | . | . | . | . | Choroid | . |
| 200111 | GEL | Male | 73 | 1 | 01NOV2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 07NOV2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 14NOV2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 21NOV2018 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 02JAN2019 | Yes | Vitreous | Normal | . | . |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 7 | 06NOV2018 | . | . | . | . | . |

Listing 7 (84 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|----------|----------|---------|
| | | | | | | Result | | |
| 200112 | DROP | Male | 85 | 1 | 09NOV2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 14NOV2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 4 | 21NOV2018 | No | Vitreous | . | |
| . | . | . | . | . | . | . | Retina | . |
| . | . | . | . | . | . | . | Macula | . |
| . | . | . | . | . | . | . | Choroid | . |
| . | . | . | 5 | 28NOV2018 | No | Vitreous | . | |
| . | . | . | . | . | . | . | Retina | . |
| . | . | . | . | . | . | . | Macula | . |
| . | . | . | . | . | . | . | Choroid | . |
| . | . | . | 6 | 09JAN2019 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 7 | 30NOV2018 | . | . | . | . |
| 200113 | DROP | Male | 77 | 1 | 09NOV2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | 3 | 14NOV2018 | No | Vitreous | . | |
| . | . | . | . | . | . | . | Retina | . |
| . | . | . | . | . | . | . | Macula | . |
| . | . | . | . | . | . | . | Choroid | . |
| . | . | . | 4 | 21NOV2018 | No | Vitreous | . | |
| . | . | . | . | . | . | . | Retina | . |
| . | . | . | . | . | . | . | Macula | . |
| . | . | . | . | . | . | . | Choroid | . |
| . | . | . | 5 | 29NOV2018 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | . | 6 | 11JAN2019 | Yes | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (85 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | Result | Comment |
|-------------|---------------|---------------|--------------|-----------|------------|-----|-----------------|---------|
| | | | | | Yes | No | | |
| 200114 | DROP | Female 64 | 1 | 23NOV2018 | Yes | No | Vitreous Normal | . |
| . | . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | . | Choroid Normal | . |
| 200115 | GEL | Female 70 | 1 | 14DEC2018 | Yes | No | Vitreous Normal | . |
| . | . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | . | Choroid Normal | . |
| . | . | . | 3 | 19DEC2018 | Yes | No | Vitreous Normal | . |
| . | . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | . | Choroid Normal | . |
| . | . | . | 4 | 27DEC2018 | Yes | No | Vitreous Normal | . |
| . | . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | . | Choroid Normal | . |
| . | . | . | 5 | 03JAN2019 | Yes | No | Vitreous Normal | . |
| . | . | . | . | . | . | . | Retina Normal | . |
| . | . | . | . | . | . | . | Macula Normal | . |
| . | . | . | . | . | . | . | Choroid Normal | . |
| . | . | . | 6 | 13FEB2019 | No | Yes | Vitreous . | . |
| . | . | . | . | . | . | . | Retina . | . |
| . | . | . | . | . | . | . | Macula . | . |
| . | . | . | . | . | . | . | Choroid . | . |
| 200201 | | Female 71 | 1 | 24JAN2018 | . | . | . | . |

Listing 7 (86 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | Visit No. | Date | Performed? | | | Comment |
|-------------|---------------|---------------|--------------|------|------------|----------|----------|----------|
| | | | | | | Result | | |
| 200202 | DROP | Female | 71 | 1 | 13JUN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 19JUN2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 25JUN2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 03JUL2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 17AUG2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Normal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 7 | 06JUL2018 | . | . | . | . | . |
| 200203 | GEL | Male | 66 | 1 | 21JUN2018 | Yes | Vitreous | Normal |
| . | . | . | . | . | . | . | Retina | Abnormal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 3 | 27JUN2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Abnormal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 4 | 02JUL2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Abnormal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 5 | 12JUL2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Abnormal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |
| . | . | 6 | 04SEP2018 | Yes | . | Vitreous | Normal | |
| . | . | . | . | . | . | . | Retina | Abnormal |
| . | . | . | . | . | . | . | Macula | Normal |
| . | . | . | . | . | . | . | Choroid | Normal |

Listing 7 (87 of 87): Ophthalmoscopy test during the study

| Sbj Code | Study Drug | Age (year) | No. | Date | Visit | | |
|-------------|---------------|---------------|-----|-----------|------------|-------------------|-------------------|
| | | | | | Performed? | Result | Comment |
| 200204 | GEL | Male | 58 | 1 | 28JUN2018 | Yes | Vitreous Normal . |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Normal . | |
| . | . | . | 3 | 04JUL2018 | Yes | Vitreous Normal . | |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Normal . | |
| . | . | . | 4 | 10JUL2018 | Yes | Vitreous Normal . | |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Normal . | |
| . | . | . | 5 | 18JUL2018 | Yes | Vitreous Normal . | |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Normal . | |
| . | . | . | 6 | 04SEP2018 | Yes | Vitreous Normal . | |
| . | . | . | . | . | . | Retina Normal . | |
| . | . | . | . | . | . | Macula Normal . | |
| . | . | . | . | . | . | Choroid Normal . | |

SAS program: L03_List_06.sas - SAS dataset name(s): RAND,DEMOGRAPHY,OPHTHALMOSCOPY

Listing 8 (1 of 9): Bromfenac treatment before surgery, Ocular surface sterilization and Surgery problems

| Bromfenac treatment administration | | | | | | | | | | |
|------------------------------------|-------|------------|-------|-----------|-----------------|---------------|--------------|------------------------------|--------------|-------------------------------------|
| Sbj | Study | Age | Visit | Which eye | 3 days involved | 2 days before | 1 day before | Ocular surface sterilization | N/Y | Procedural problem and complication |
| Code | drug | Sex (year) | No. | Date | involved | before | before | sterilization | Proc.problem | Complication |
| 100101 | DROP | Female 84 | 2 | 25OCT2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100102 | GEL | Male 80 | 2 | 31OCT2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100103 | | Female 70 | 1 | . | . | . | . | . | . | . |
| 100104 | GEL | Male 70 | 2 | 07NOV2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100105 | DROP | Female 85 | 2 | 08NOV2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100106 | GEL | Male 56 | 2 | 15NOV2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100107 | DROP | Female 82 | 2 | 28NOV2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100108 | DROP | Female 73 | 2 | 06DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100109 | GEL | Female 56 | 2 | 12DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100110 | DROP | Female 75 | 2 | 13DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100111 | DROP | Female 60 | 2 | 13DEC2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100112 | GEL | Male 73 | 2 | 03JAN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100113 | GEL | Female 77 | 2 | 03JAN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100114 | GEL | Male 64 | 2 | 03JAN2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100115 | DROP | Male 76 | 2 | 04JAN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100116 | GEL | Male 62 | 2 | 04JAN2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100117 | DROP | Female 51 | 2 | 10JAN2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100118 | DROP | Female 78 | 2 | 17JAN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100119 | DROP | Female 72 | 2 | 24JAN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100120 | GEL | Male 79 | 2 | 24JAN2018 | Left eye | Yes | Yes | Yes | Yes | No |

Listing 8 (2 of 9): Bromfenac treatment before surgery, Ocular surface sterilization and Surgery problems

| Bromfenac treatment administration | | | | | | | | | | |
|------------------------------------|-------|------------|-------|-----------|-----------------|---------------|--------------|------------------------------|--------------|-------------------------------------|
| Sbj | Study | Age | Visit | Which eye | 3 days involved | 2 days before | 1 day before | Ocular surface sterilization | N/Y | Procedural problem and complication |
| Code | drug | Sex (year) | No. | Date | involved | before | before | sterilization | Proc.problem | Complication |
| 100121 | GEL | Male 80 | 2 | 24JAN2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100122 | DROP | Female 76 | 2 | 25JAN2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100123 | DROP | Female 76 | 2 | 25JAN2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100124 | GEL | Female 71 | 2 | 01FEB2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100125 | GEL | Female 62 | 2 | 01FEB2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100126 | GEL | Female 85 | 2 | 07FEB2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100127 | GEL | Female 68 | 2 | 08FEB2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100128 | DROP | Male 80 | 2 | 08FEB2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100129 | DROP | Female 78 | 2 | 08FEB2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100130 | GEL | Male 66 | 2 | 21FEB2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100131 | DROP | Female 77 | 2 | 21FEB2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100132 | DROP | Male 69 | 2 | 07MAR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100133 | GEL | Male 74 | 2 | 07MAR2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100134 | DROP | Female 66 | 2 | 07MAR2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100135 | GEL | Male 69 | 2 | 15MAR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100136 | GEL | Female 90 | 2 | 05APR2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100137 | DROP | Female 62 | 2 | 19APR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100138 | GEL | Male 63 | 2 | 19APR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100139 | DROP | Female 71 | 2 | 26APR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100140 | GEL | Male 81 | 2 | 02MAY2018 | Right eye | Yes | Yes | Yes | Yes | No |

Listing 8 (3 of 9): Bromfenac treatment before surgery, Ocular surface sterilization and Surgery problems

| Bromfenac treatment administration | | | | | | | | | | |
|------------------------------------|-------|------------|-------|-----------|-----------------|---------------|--------------|------------------------------|--------------|-------------------------------------|
| Sbj | Study | Age | Visit | Which eye | 3 days involved | 2 days before | 1 day before | Ocular surface sterilization | N/Y | Procedural problem and complication |
| Code | drug | Sex (year) | No. | Date | | | | | Proc.problem | Complication |
| 100141 | DROP | Female 74 | 2 | 02MAY2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100142 | GEL | Female 77 | 2 | 16MAY2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100143 | GEL | Male 74 | 2 | 20JUN2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100144 | DROP | Female 89 | 2 | 27JUN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100145 | GEL | Male 81 | 2 | 04JUL2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100146 | GEL | Male 71 | 2 | 21AUG2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100147 | DROP | Male 48 | 2 | 28AUG2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100148 | DROP | Female 83 | 2 | 30AUG2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100149 | DROP | Female 71 | 2 | 30AUG2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100150 | GEL | Female 77 | 2 | 05SEP2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100151 | DROP | Female 67 | 2 | 04OCT2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100152 | GEL | Female 78 | 2 | 04OCT2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100153 | DROP | Female 81 | 2 | 17OCT2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100154 | GEL | Female 68 | 2 | 18OCT2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100155 | DROP | Female 79 | 2 | 18OCT2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100156 | GEL | Female 69 | 2 | 18OCT2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100201 | GEL | Female 80 | 2 | 07DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100202 | DROP | Female 70 | 2 | 07DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100203 | DROP | Female 76 | 2 | 14DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100204 | GEL | Male 71 | 2 | 14DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |

Listing 8 (4 of 9): Bromfenac treatment before surgery, Ocular surface sterilization and Surgery problems

| Bromfenac treatment administration | | | | | | | | | | |
|------------------------------------|-------|------------|-------|-----------|-----------------|---------------|--------------|------------------------------|--------------|-------------------------------------|
| Sbj | Study | Age | Visit | Which eye | 3 days involved | 2 days before | 1 day before | Ocular surface sterilization | N/Y | Procedural problem and complication |
| Code | drug | Sex (year) | No. | Date | involved | before | before | sterilization | Proc.problem | Complication |
| 100205 | GEL | Male 75 | 2 | 08FEB2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100206 | DROP | Female 81 | 2 | 11JAN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100207 | DROP | Female 65 | 2 | 11JAN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100208 | GEL | Female 79 | 2 | 11JAN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100209 | GEL | Female 77 | 2 | 18JAN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100210 | DROP | Female 70 | 2 | 18JAN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100211 | GEL | Male 67 | 2 | 18JAN2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100212 | DROP | Female 82 | 2 | 18JAN2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100213 | DROP | Female 81 | 2 | 01FEB2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100214 | DROP | Female 77 | 2 | 08FEB2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100215 | GEL | Female 83 | 2 | 08FEB2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100216 | GEL | Female 74 | 2 | 15FEB2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100217 | DROP | Female 72 | 2 | 08MAR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100218 | DROP | Male 72 | 2 | 08MAR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100219 | GEL | Female 83 | 2 | 15MAR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100220 | GEL | Male 64 | 2 | 15MAR2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100221 | GEL | Female 76 | 2 | 05APR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100222 | DROP | Female 76 | 2 | 12APR2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100223 | DROP | Male 61 | 2 | 12APR2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100224 | GEL | Female 75 | 2 | 26APR2018 | Right eye | Yes | Yes | Yes | Yes | No |

Listing 8 (5 of 9): Bromfenac treatment before surgery, Ocular surface sterilization and Surgery problems

| Bromfenac treatment administration | | | | | | | | | |
|------------------------------------|-------|------------|-------|-----------|-----------------|---------------|--------------|------------------------------|-------------------------------------|
| Sbj | Study | Age | Visit | Which eye | 3 days involved | 2 days before | 1 day before | Ocular surface sterilization | Procedural problem and complication |
| Code | drug | Sex (year) | No. | Date | | | | N/Y | Proc.problem Complication |
| 100225 | DROP | Female 79 | 2 | 26APR2018 | Right eye | Yes | Yes | Yes | Yes No |
| 100226 | GEL | Female 74 | 2 | 26APR2018 | Right eye | Yes | Yes | Yes | Yes No |
| 100227 | DROP | Female 68 | 2 | 03MAY2018 | Left eye | Yes | Yes | Yes | Yes No |
| 100228 | GEL | Female 68 | 2 | 03MAY2018 | Right eye | Yes | Yes | Yes | Yes No |
| 100229 | GEL | Female 70 | 2 | 10MAY2018 | Left eye | Yes | Yes | Yes | Yes No |
| 100230 | GEL | Female 63 | 2 | 10MAY2018 | Left eye | Yes | Yes | Yes | Yes No |
| 100231 | DROP | Female 74 | 2 | 10MAY2018 | Right eye | Yes | Yes | Yes | Yes No |
| 100232 | DROP | Female 73 | 2 | 10MAY2018 | Left eye | Yes | Yes | Yes | Yes No |
| 100233 | GEL | Female 72 | 2 | 24MAY2018 | Left eye | Yes | Yes | Yes | Yes No |
| 100234 | GEL | Female 73 | 2 | 24MAY2018 | Right eye | Yes | Yes | Yes | Yes No |
| 100235 | DROP | Male 64 | 2 | 31MAY2018 | Right eye | Yes | Yes | Yes | Yes No |
| 100236 | DROP | Female 70 | 2 | 31MAY2018 | Right eye | Yes | Yes | Yes | Yes No |
| 100237 | DROP | Male 73 | 2 | 07JUN2018 | Left eye | Yes | Yes | Yes | Yes No |
| 100238 | GEL | Male 78 | 2 | 07JUN2018 | Right eye | Yes | Yes | Yes | Yes No |
| 100239 | DROP | Female 80 | 2 | 14JUN2018 | Right eye | Yes | Yes | Yes | Yes No |
| 100240 | | Female 72 | 1 | . | . | . | . | . | . |
| 100241 | GEL | Female 74 | 2 | 25OCT2018 | Left eye | Yes | Yes | Yes | Yes No |
| 100242 | GEL | Female 67 | 2 | 08NOV2018 | Right eye | Yes | Yes | Yes | Yes No |
| 100243 | DROP | Male 74 | 2 | 06DEC2018 | Right eye | Yes | Yes | Yes | Yes No |
| 100244 | GEL | Female 66 | 2 | 13DEC2018 | Left eye | Yes | Yes | Yes | Yes No |

Listing 8 (6 of 9): Bromfenac treatment before surgery, Ocular surface sterilization and Surgery problems

| Bromfenac treatment administration | | | | | | | | | | |
|------------------------------------|-------|------------|-------|-----------|-----------------|---------------|--------------|------------------------------|--------------|-------------------------------------|
| Sbj | Study | Age | Visit | Which eye | 3 days involved | 2 days before | 1 day before | Ocular surface sterilization | N/Y | Procedural problem and complication |
| Code | drug | Sex (year) | No. | Date | | | | | Proc.problem | Complication |
| 100245 | DROP | Female 69 | 2 | 13DEC2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100301 | GEL | Female 68 | 2 | 19OCT2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100302 | GEL | Male 61 | 2 | 02NOV2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100303 | DROP | Female 73 | 2 | 02NOV2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100304 | DROP | Male 58 | 2 | 16NOV2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100305 | DROP | Female 85 | 2 | 16NOV2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100306 | DROP | Female 84 | 2 | 22NOV2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100307 | GEL | Female 73 | 2 | 29NOV2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100308 | GEL | Female 85 | 2 | 29NOV2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100309 | DROP | Female 61 | 2 | 29NOV2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100310 | GEL | Female 73 | 2 | 30NOV2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100311 | GEL | Female 83 | 2 | 05DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100312 | DROP | Female 71 | 2 | 05DEC2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100313 | GEL | Male 71 | 2 | 04DEC2017 | Right eye | Yes | Yes | Yes | Yes | BREAKAGE POSTERIOR CAPSULE |
| 100314 | DROP | Male 67 | 2 | 05DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100315 | GEL | Female 65 | 2 | 05DEC2017 | Right eye | Yes | Yes | Yes | No | No |
| 100316 | DROP | Male 76 | 2 | 05DEC2017 | Left eye | Yes | Yes | Yes | No | No |
| 100317 | GEL | Male 85 | 2 | 05DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100318 | GEL | Female 80 | 2 | 05DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100319 | DROP | Male 70 | 2 | 05DEC2017 | Left eye | Yes | Yes | Yes | Yes | No |

Listing 8 (7 of 9): Bromfenac treatment before surgery, Ocular surface sterilization and Surgery problems

| Bromfenac treatment administration | | | | | | | | | | |
|------------------------------------|-------|------------|-------|-----------|-----------------|---------------|--------------|------------------------------|--------------|-------------------------------------|
| Sbj | Study | Age | Visit | Which eye | 3 days involved | 2 days before | 1 day before | Ocular surface sterilization | N/Y | Procedural problem and complication |
| Code | drug | Sex (year) | No. | Date | involved | before | before | sterilization | Proc.problem | Complication |
| 100320 | DROP | Male 69 | 2 | 05DEC2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100321 | GEL | Male 72 | 2 | 11DEC2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100322 | GEL | Male 80 | 2 | 13DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100323 | DROP | Female 76 | 2 | 13DEC2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100324 | DROP | Male 65 | 2 | 18DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100325 | GEL | Female 83 | 2 | 18DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100326 | DROP | Male 81 | 2 | 18DEC2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100327 | GEL | Female 73 | 2 | 18DEC2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100328 | DROP | Male 82 | 2 | 18DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100329 | GEL | Male 74 | 2 | 18DEC2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100330 | DROP | Male 61 | 2 | 19DEC2017 | Left eye | Yes | Yes | Yes | Yes | No |
| 100331 | GEL | Female 71 | 2 | 19DEC2017 | Right eye | Yes | Yes | Yes | Yes | No |
| 100332 | DROP | Male 82 | 2 | 12JAN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100333 | DROP | Male 62 | 2 | 25JAN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100334 | GEL | Male 72 | 2 | 24JAN2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100335 | DROP | Female 80 | 2 | 06FEB2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100336 | GEL | Female 82 | 2 | 06MAR2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100337 | GEL | Male 72 | 2 | 16MAR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| BREAKAGE OF THE POSTERIOR CAPSULE | | | | | | | | | | |
| 100338 | DROP | Female 87 | 2 | 21MAR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100339 | GEL | Male 56 | 2 | 28MAR2018 | Left eye | Yes | Yes | Yes | Yes | No |

Listing 8 (8 of 9): Bromfenac treatment before surgery, Ocular surface sterilization and Surgery problems

| Bromfenac treatment administration | | | | | | | | | | |
|------------------------------------|-------|------------|-------|-----------|-----------------|---------------|--------------|------------------------------|--------------|-------------------------------------|
| Sbj | Study | Age | Visit | Which eye | 3 days involved | 2 days before | 1 day before | Ocular surface sterilization | N/Y | Procedural problem and complication |
| Code | drug | Sex (year) | No. | Date | involved | before | before | | Proc.problem | Complication |
| 100340 | DROP | Male 83 | 2 | 12APR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100341 | GEL | Male 88 | 2 | 12APR2018 | Left eye | No | No | No | Yes | No |
| 100342 | DROP | Female 86 | 2 | 12APR2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100343 | GEL | Male 74 | 2 | 10APR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100344 | DROP | Female 68 | 2 | 10APR2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100345 | GEL | Male 48 | 2 | 10APR2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100346 | DROP | Female 77 | 2 | 12APR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100347 | GEL | Male 58 | 2 | 18APR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100348 | GEL | Female 38 | 2 | 24APR2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100349 | DROP | Male 71 | 2 | 24MAY2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100350 | DROP | Female 67 | 2 | 22MAY2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100351 | GEL | Female 79 | 2 | 25MAY2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100352 | DROP | Female 63 | 2 | 29MAY2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 100353 | GEL | Female 72 | 2 | 07JUN2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100354 | GEL | Female 80 | 2 | 07JUN2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100355 | DROP | Female 80 | 2 | 13JUN2018 | Left eye | Yes | Yes | Yes | Yes | No |
| 100356 | GEL | Male 74 | 2 | 18JUN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 200101 | GEL | Female 66 | 2 | 16JAN2018 | Left eye | No | No | Yes | Yes | No |
| 200102 | DROP | Female 76 | 2 | 30JAN2018 | Right eye | Yes | Yes | Yes | Yes | No |
| 200103 | DROP | Male 82 | 2 | 13FEB2018 | Right eye | Yes | No | No | Yes | No |

Listing 8 (9 of 9): Bromfenac treatment before surgery, Ocular surface sterilization and Surgery problems

| Bromfenac treatment administration | | | | | | | | | | Procedural problem and complication | | |
|------------------------------------|-------|------------|-------|-----------|-----------------|---------------|--------------|------------------------------|-----|-------------------------------------|--------------|--|
| Sbj | Study | Age | Visit | Which eye | 3 days involved | 2 days before | 1 day before | Ocular surface sterilization | N/Y | Proc.problem | Complication | |
| Code | drug | Sex (year) | No. | Date | | | | | | | | |
| 200104 | GEL | Female 78 | 2 | 08MAY2018 | Right eye | Yes | Yes | Yes | Yes | No | | |
| 200105 | GEL | Female 65 | 2 | 29MAY2018 | Right eye | Yes | Yes | Yes | Yes | No | | |
| 200106 | DROP | Female 75 | 2 | 26JUN2018 | Left eye | Yes | Yes | Yes | Yes | No | | |
| 200107 | DROP | Female 54 | 2 | 03JUL2018 | Left eye | Yes | No | No | Yes | No | | |
| 200108 | GEL | Male 77 | 2 | 04SEP2018 | Left eye | Yes | Yes | Yes | Yes | No | | |
| 200109 | GEL | Female 84 | 2 | 02OCT2018 | Right eye | Yes | Yes | Yes | Yes | No | | |
| 200110 | DROP | Male 64 | 2 | 09OCT2018 | Right eye | Yes | Yes | Yes | Yes | No | | |
| 200111 | GEL | Male 73 | 2 | 06NOV2018 | Left eye | Yes | Yes | Yes | Yes | No | | |
| 200112 | DROP | Male 85 | 2 | 13NOV2018 | Left eye | Yes | Yes | Yes | Yes | No | | |
| 200113 | DROP | Male 77 | 2 | 13NOV2018 | Left eye | Yes | Yes | Yes | Yes | No | | |
| 200114 | DROP | Female 64 | 2 | 27NOV2018 | Right eye | Yes | Yes | Yes | Yes | No | | |
| 200115 | GEL | Female 70 | 2 | 18DEC2018 | Left eye | Yes | Yes | Yes | Yes | No | | |
| 200201 | | Female 71 | 1 | . | . | . | . | . | . | . | | |
| 200202 | DROP | Female 71 | 2 | 18JUN2018 | Right eye | Yes | Yes | Yes | Yes | No | | |
| 200203 | GEL | Male 66 | 2 | 26JUN2018 | Left eye | Yes | Yes | Yes | Yes | No | | |
| 200204 | GEL | Male 58 | 2 | 03JUL2018 | Left eye | Yes | Yes | Yes | Yes | No | | |

SAS program: L03_List_08.sas - SAS dataset name(s): RAND,DEMOGRAPHY,SURGERY,BROM_TRT

Listing 9 (1 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|-------------------------------------|--|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100101 | DROP | Female | 84 | 1 | 20OCT2017 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3% 1 3 TIMES PER DAY |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | 2 | 25OCT2017 | Name Dosage Unit Frequency | MYDRIASERT 1 1 ONCE |
| 100102 | GEL | Male | 80 | 1 | 27OCT2017 | Name Dosage Unit Frequency | NETILMICIN 0.3 % 5 ml 3 TIMES PER DAY |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | 2 | 31OCT2017 | Name Dosage Unit Frequency | TROPICAMIDE 1 % 3 AS NEEDED |
| 100104 | GEL | Male | 70 | 1 | 03NOV2017 | Name Dosage Unit Frequency | NETILMICIN 0.3 % 5 ml 3 TIMES PER DAY |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | 2 | 07NOV2017 | Name Dosage Unit Frequency | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) 5.4 MG 1 ONCE |
| 100105 | DROP | Female | 85 | 1 | 03NOV2017 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3% 1 3 TIMES PER DAY |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | 2 | 08NOV2017 | Name Dosage Unit Frequency | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) 0.28/5,4 MG 1 ONCE |

Listing 9 (2 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|--|---|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100106 | GEL | Male | 56 | 1 | 09NOV2017 | Name Dosage Unit Frequency | NETLIMICIN 0.3 % 1 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| . | . | . | . | 2 | 15NOV2017 | Dosage 5.4 MG | |
| . | . | . | . | . | | Unit 1 | |
| . | . | . | . | . | | Frequency ONCE | |
| 100107 | DROP | Female | 82 | 1 | 23NOV2017 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 5 ml 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| . | . | . | . | 2 | 28NOV2017 | Dosage 0.28/5.4 | |
| . | . | . | . | . | | Unit mg | |
| . | . | . | . | . | | Frequency ONCE | |
| 100108 | DROP | Female | 73 | 1 | 01DEC2017 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 1 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| . | . | . | . | 2 | 06DEC2017 | Dosage 5.4 MG | |
| . | . | . | . | . | | Unit 1 | |
| . | . | . | . | . | | Frequency ONCE | |
| 100109 | GEL | Female | 56 | 1 | 07DEC2017 | Name Dosage Unit Frequency | NETILMICIN 0.3% 1 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| . | . | . | . | 2 | 12DEC2017 | Dosage 0.28/5.4 MG | |
| . | . | . | . | . | | Unit 1 | |
| . | . | . | . | . | | Frequency ONCE | |

Listing 9 (3 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|--|---|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100110 | DROP | Female | 75 | 1 | 07DEC2017 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3% 1 3 TIMES PER DAY |
| | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| | . | . | . | . | | Dosage 0.28/5.4 MG | |
| | . | . | . | . | | Unit 1 | |
| | . | . | . | . | | Frequency ONCE | |
| 100111 | DROP | Female | 60 | 1 | 07DEC2017 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3% 1 3 TIMES PER DAY |
| | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| | . | . | . | . | | Dosage 0.28/5.4 MG | |
| | . | . | . | . | | Unit 1 | |
| | . | . | . | . | | Frequency ONCE | |
| 100112 | GEL | Male | 73 | 1 | 28DEC2017 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3% 1 3 TIMES PER DAY |
| | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| | . | . | . | . | | Dosage 0.28/5,4 MG | |
| | . | . | . | . | | Unit 1 | |
| | . | . | . | . | | Frequency ONCE | |
| 100113 | GEL | Female | 77 | 1 | 28DEC2017 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3% 1 3 TIMES PER DAY |
| | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| | . | . | . | . | | Dosage 0.28/5,4 MG | |
| | . | . | . | . | | Unit 1 | |
| | . | . | . | . | | Frequency ONCE | |

Listing 9 (4 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|--|---|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100114 | GEL | Male | 64 | 1 | 29DEC2017 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3% 1 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| . | . | . | . | . | | Dosage 0.28/5,4 MG | |
| . | . | . | . | . | | Unit 1 | |
| . | . | . | . | . | | Frequency ONCE | |
| 100115 | DROP | Male | 76 | 1 | 29DEC2017 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3% 1 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| . | . | . | . | . | | Dosage 0.28/5,4 MG | |
| . | . | . | . | . | | Unit 1 | |
| . | . | . | . | . | | Frequency ONCE | |
| 100116 | GEL | Male | 62 | 1 | 29DEC2017 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3% 1 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| . | . | . | . | . | | Dosage 0.28/5,4 MG | |
| . | . | . | . | . | | Unit 1 | |
| . | . | . | . | . | | Frequency ONCE | |
| 100117 | DROP | Female | 51 | 1 | 04JAN2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3% 1 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| . | . | . | . | . | | Dosage 0.28/5,4 MG | |
| . | . | . | . | . | | Unit 1 | |
| . | . | . | . | . | | Frequency ONCE | |

Listing 9 (5 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|--|---|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100118 | DROP | Female | 78 | 1 | 11JAN2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3% ml 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| . | . | . | . | 2 | 17JAN2018 | Dosage Unit Frequency | 0.28/5,4 mg ONCE |
| 100119 | DROP | Female | 72 | 1 | 19JAN2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3% ml 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| . | . | . | . | 2 | 24JAN2018 | Dosage Unit Frequency | 0.28/5,4 mg ONCE |
| 100120 | GEL | Male | 79 | 1 | 19JAN2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 5 ml 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| . | . | . | . | 2 | 24JAN2018 | Dosage Unit Frequency | 0.28/ 5.4 mg ONCE |
| 100121 | GEL | Male | 80 | 1 | 19JAN2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3% ml 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT | |
| . | . | . | . | 2 | 24JAN2018 | Dosage Unit Frequency | 0.28/5.4 mg ONCE |

Listing 9 (6 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|--|--|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100122 | DROP | Female | 76 | 1 | 19JAN2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| | | . | . | . | . | MYDRIASERT (PHENYLEPHRINE/TROPICAMIDE) | |
| | | . | . | 2 | 25JAN2018 | Dosage Unit Frequency | 0.28+5.4 mg ONCE |
| 100123 | DROP | Female | 76 | 1 | 19JAN2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| | | . | . | . | . | MYDRIASERT (PHENYLEFRINE/TROPICAMIDE) | |
| | | . | . | 2 | 25JAN2018 | Dosage Unit Frequency | 0.28+4.5 mg ONCE |
| 100124 | GEL | Female | 71 | 1 | 26JAN2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| | | . | . | . | . | MYDRIASERT (PHENYLEPHRINE/TROPICAMIDE) | |
| | | . | . | 2 | 01FEB2018 | Dosage Unit Frequency | 0.25 + 4.8 mg ONCE |
| 100125 | GEL | Female | 62 | 1 | 26JAN2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| | | . | . | . | . | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| | | . | . | 2 | 01FEB2018 | Dosage Unit Frequency | 0.28/5,4 mg ONCE |

Listing 9 (7 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|--|--|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100126 | GEL | Female | 85 | 1 | 02FEB2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| | . | . | . | . | | Dosage Unit Frequency | 0.28/5,4 mg ONCE |
| 100127 | GEL | Female | 68 | 1 | 02FEB2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| | . | . | . | . | | MYDRIASERT | |
| | . | . | . | . | | Dosage Unit Frequency | 0.28 + 5.4 mg ONCE |
| 100128 | DROP | Male | 80 | 1 | 02FEB2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| | . | . | . | . | | MYDRIASERT | |
| | . | . | . | . | | Dosage Unit Frequency | 0.28 + 5.4 mg ONCE |
| 100129 | DROP | Female | 78 | 1 | 02FEB2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| | . | . | . | . | | MYDRIASERT | |
| | . | . | . | . | | Dosage Unit Frequency | 0.28 + 5.4 mg ONCE |

Listing 9 (8 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|--|--|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100130 | GEL | Male | 66 | 1 | 16FEB2018 | Name Dosage Unit Frequency | NETILMICIN 0.3 % 3 TIMES PER DAY |
| | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| | . | . | . | . | | Dosage Unit Frequency | 0.28 + 5.4 mg ONCE |
| 100131 | DROP | Female | 77 | 1 | 16FEB2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| | . | . | . | . | | Dosage Unit Frequency | 0.28/5,4 mg ONCE |
| 100132 | DROP | Male | 69 | 1 | 02MAR2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| | . | . | . | . | | Dosage Unit Frequency | 0.28/5,4 mg ONCE |
| 100133 | GEL | Male | 74 | 1 | 02MAR2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| | . | . | . | . | | Dosage Unit Frequency | 0.28/5,4 mg ONCE |

Listing 9 (9 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|--|--|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100134 | DROP | Female | 66 | 1 | 02MAR2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| . | . | . | . | 2 | 07MAR2018 | Dosage Unit Frequency | 0.28/5,4 mg ONCE |
| 100135 | GEL | Male | 69 | 1 | 09MAR2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| . | . | . | . | 2 | 15MAR2018 | Dosage Unit Frequency | 0.28/5,4 mg ONCE |
| 100136 | GEL | Female | 90 | 1 | 30MAR2018 | Name Dosage Unit Frequency | NETILMICIN 0.3 % 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (PHENYLEPHRINE/TROPICAMIDE) | |
| . | . | . | . | 2 | 05APR2018 | Dosage Unit Frequency | 5.4 + 0.28 mg ONCE |
| 100137 | DROP | Female | 62 | 1 | 13APR2018 | Name Dosage Unit Frequency | NETILMICIN 0.3 % 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (PHENYLEPHRINE/TROPICAMIDE) | |
| . | . | . | . | 2 | 19APR2018 | Dosage Unit Frequency | 5.4 + 0.28 mg ONCE |

Listing 9 (10 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|--|--|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100138 | GEL | Male | 63 | 1 | 13APR2018 | Name Dosage Unit Frequency | NETILMICIN 0.3 % 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (PHENYLEPHRINE/TROPICAMIDE) | |
| . | . | . | . | 2 | 19APR2018 | Dosage Unit Frequency | 5.4 + 0.28 MG ONCE |
| 100139 | DROP | Female | 71 | 1 | 20APR2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (PHENYLEPHRINE/TROPICAMIDE) | |
| . | . | . | . | 2 | 26APR2018 | Dosage Unit Frequency | 5.4 + 0.28 mg ONCE |
| 100140 | GEL | Male | 81 | 1 | 27APR2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (PHENYLEPHRINE/TROPICAMIDE) | |
| . | . | . | . | 2 | 02MAY2018 | Dosage Unit Frequency | 5.4 + 0.28 mg ONCE |
| 100141 | DROP | Female | 74 | 1 | 27APR2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % ONCE |
| . | . | . | . | . | | MYDRIASERT (PHENYLEPHRINE/TROPICAMIDE) | |
| . | . | . | . | 2 | 02MAY2018 | Dosage Unit Frequency | 5.4 + 0.28 mg ONCE |

Listing 9 (11 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|--|--|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100142 | GEL | Female | 77 | 1 | 11MAY2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (PHENYLEPHRINE/TROPICAMIDE) | |
| . | . | . | . | 2 | 16MAY2018 | Dosage Unit Frequency | 5.4 + 0.28 mg ONCE |
| 100143 | GEL | Male | 74 | 1 | 15JUN2018 | Name Dosage Unit Frequency | NETILMICIN 0.3 ml 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT(TROPICAMIDE/PHENYLEFRINE) | |
| . | . | . | . | 2 | 20JUN2018 | Dosage Unit Frequency | 0.28/4.5 mg ONCE |
| 100144 | DROP | Female | 89 | 1 | 22JUN2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT(TROPICAMIDE/PHENYLEFRINE) | |
| . | . | . | . | 2 | 27JUN2018 | Dosage Unit Frequency | 0.28/4.5 mg ONCE |
| 100145 | GEL | Male | 81 | 1 | 29JUN2018 | Name Dosage Unit Frequency | NETTACIN COLL 0.3 % 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (TROPICAMIDE/PHENYLEPHRINE) | |
| . | . | . | . | 2 | 04JUL2018 | Dosage Unit Frequency | 0.28/5.4 mg ONCE |

Listing 9 (12 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|---------------------------------------|---|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100146 | GEL | Male | 71 | 1 | 17AUG2018 | Name Dosage Unit Frequency | NETILMICIN 0.3 % 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (PHENYLEFRINE/TROPICAMIDE) | |
| . | . | . | . | 2 | 21AUG2018 | Dosage Unit Frequency | 0.28/5.4 mg ONCE |
| 100147 | DROP | Male | 48 | 1 | 24AUG2018 | Name Dosage Unit Frequency | NETILMICIN 0.3 % 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (PHENYLEFRINE/TROPICAMIDE) | |
| . | . | . | . | 2 | 28AUG2018 | Dosage Unit Frequency | 0.28/5.4 mg ONCE |
| 100148 | DROP | Female | 83 | 1 | 24AUG2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (PHENYLEFRINE/TROPICAMIDE) | |
| . | . | . | . | 2 | 30AUG2018 | Dosage Unit Frequency | 0.28/5.4 mg ONCE |
| 100149 | DROP | Female | 71 | 1 | 24AUG2018 | Name Dosage Unit Frequency | NETILMICIN COLL 0.3 % 3 TIMES PER DAY |
| . | . | . | . | . | | MYDRIASERT (PHENYLEFRINE/TROPICAMIDE) | |
| . | . | . | . | 2 | 30AUG2018 | Dosage Unit Frequency | 0.28/5.4 mg ONCE |
| 100150 | GEL | Female | 77 | 2 | 05SEP2018 | Name Dosage Unit Frequency | MYDRIASERT (PHENYLEFRINE/TROPICAMIDE) 0.28/5.4 mg ONCE |

Listing 9 (13 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|---------------------------------------|---|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100151 | DROP | Female | 67 | 1 | 28SEP2018 | Name Dosage Unit Frequency | NETIDEX 3 mg ONCE |
| | . | . | . | . | | MYDRIASERT (PHENYLEFRINE/TROPICAMIDE) | |
| | . | . | . | . | | Dosage 0.28/5.4 | |
| | . | . | . | . | | Unit mg | |
| | . | . | . | . | | Frequency ONCE | |
| 100152 | GEL | Female | 78 | 2 | 04OCT2018 | Name Dosage Unit Frequency | MYDRIASERT (PHENYLEFRINE/TROPICAMIDE) 0.28/5.4 mg ONCE |
| 100153 | DROP | Female | 81 | 1 | 12OCT2018 | Name Dosage Unit Frequency | NETILDEX 3 mg ONCE |
| | . | . | . | . | | MYDRIASERT (PHENYLEFRINE/TROPICAMIDE) | |
| | . | . | . | . | | Dosage 0.28/5.4 | |
| | . | . | . | . | | Unit mg | |
| | . | . | . | . | | Frequency ONCE | |
| 100154 | GEL | Female | 68 | 1 | 12OCT2018 | Name Dosage Unit Frequency | NETILDEX 3 mg ONCE |
| | . | . | . | . | | MYDRIASERT (PHENYLEFRINE/TROPICAMIDE) | |
| | . | . | . | . | | Dosage 0.28/5.4 | |
| | . | . | . | . | | Unit mg | |
| | . | . | . | . | | Frequency ONCE | |
| 100155 | DROP | Female | 79 | 1 | 12OCT2018 | Name Dosage Unit Frequency | NETILDEX 3 mg ONCE |
| | . | . | . | . | | MYDRIASERT (PHENYLEFRINE/TROPICAMIDE) | |
| | . | . | . | . | | Dosage 0.28/5.4 | |
| | . | . | . | . | | Unit mg | |
| | . | . | . | . | | Frequency ONCE | |

Listing 9 (14 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|-------------------------------------|---|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100156 | GEL | Female | 69 | 1 | 12OCT2018 | Name Dosage Unit Frequency | NETILDEX 3 mg ONCE |
| | . | . | . | . | | | |
| | . | . | . | . | | | |
| | . | . | . | 2 | 18OCT2018 | Name Dosage Unit Frequency | MYDRIASERT (PHENYLEFRINE/TROPICAMIDE) 0.28/5.4 mg ONCE |
| | . | . | . | . | | | |
| | . | . | . | . | | | |
| 100201 | GEL | Female | 80 | 1 | 01DEC2017 | Name Dosage Unit Frequency | LEVOFLOXACINA EYE DROPS 5 mg/ml 4 TIMES PER DAY |
| | . | . | . | . | | | |
| | . | . | . | . | | | |
| | . | . | . | 2 | 07DEC2017 | Name Dosage Unit Frequency | TROPICAMIDE + PHENYLEPHRINE 100+5 mg/ml ONCE |
| | . | . | . | . | | | |
| | . | . | . | . | | | |
| 100202 | DROP | Female | 70 | 2 | 07DEC2017 | Name Dosage Unit Frequency | VISUMDRIATIC FENILEFRINA 1 drop ONCE |
| | . | . | . | . | | | |
| | . | . | . | . | | | |
| 100203 | DROP | Female | 76 | 1 | 07DEC2017 | Name Dosage Unit Frequency | LEVOFLOXACIN EYE DROPS 5 mg/ml 4 TIMES PER DAY |
| | . | . | . | . | | | |
| | . | . | . | . | | | |
| | . | . | . | 2 | 14DEC2017 | Name Dosage Unit Frequency | VISUMDRIATIC FENILEFRINA 1 drop ONCE |
| | . | . | . | . | | | |
| | . | . | . | . | | | |
| 100204 | GEL | Male | 71 | 1 | 07DEC2017 | Name Dosage Unit Frequency | LEVOFLOXACIN EYE DROPS 5 mg/ml 4 TIMES PER DAY |
| | . | . | . | . | | | |
| | . | . | . | . | | | |
| | . | . | . | 2 | 14DEC2017 | Name Dosage Unit Frequency | VISUMDRIATIC FENILEFRINA 1 drop ONCE |
| | . | . | . | . | | | |
| | . | . | . | . | | | |

Listing 9 (15 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|-------------------------------------|---|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100205 | GEL | Male | 75 | 1 | 14DEC2017 | Name Dosage Unit Frequency | LEVOFLOXACIN EYE DROPS 5 mg/ml 4 TIMES PER DAY |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | . | | Dosage 1 | |
| | . | . | . | . | | Unit drop | |
| | . | . | . | . | | Frequency ONCE | |
| 100206 | DROP | Female | 81 | 1 | 05JAN2018 | Name Dosage Unit Frequency | LEVOFLOXACIN EYE DROPS 5 mg/ml 4 TIMES PER DAY |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | . | | Dosage 1 | |
| | . | . | . | . | | Unit drop | |
| | . | . | . | . | | Frequency ONCE | |
| 100207 | DROP | Female | 65 | 2 | 11JAN2018 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 1 drop ONCE |
| 100208 | GEL | Female | 79 | 1 | 05JAN2018 | Name Dosage Unit Frequency | LEVOFLOXACIN EYE DROPS 5 mg/ml 4 TIMES PER DAY |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | . | | Dosage 1 | |
| | . | . | . | . | | Unit drop | |
| | . | . | . | . | | Frequency ONCE | |
| 100209 | GEL | Female | 77 | 2 | 18JAN2018 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 1 drop ONCE |

Listing 9 (16 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|----------------|---------------------------|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100210 | DROP | Female | 70 | 1 | 12JAN2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | mg/ml |
| . | . | . | . | 2 | 18JAN2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | drop |
| . | . | . | . | . | . | Frequency | ONCE |
| 100211 | GEL | Male | 67 | 1 | 12JAN2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | mg/ml |
| . | . | . | . | 2 | 18JAN2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | drop |
| . | . | . | . | . | . | Frequency | ONCE |
| 100212 | DROP | Female | 82 | 1 | 12JAN2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | MG/ML |
| . | . | . | . | 2 | 18JAN2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | drop |
| . | . | . | . | . | . | Frequency | ONCE |
| 100213 | DROP | Female | 81 | 1 | 25JAN2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | mg/ml |
| . | . | . | . | 2 | 01FEB2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | drop |
| . | . | . | . | . | . | Frequency | ONCE |

Listing 9 (17 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|--|---|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100214 | DROP | Female | 77 | 1 | 05FEB2018 | Name Dosage Unit Frequency | LEVOFLOXACIN EYE DROPS 5 mg/ml 4 TIMES PER DAY |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | 2 | 08FEB2018 | Dosage Unit Frequency | 1 drop ONCE |
| 100215 | GEL | Female | 83 | 2 | 08FEB2018 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 1 drop ONCE |
| 100216 | GEL | Female | 74 | 1 | 09FEB2018 | Name Dosage Unit Frequency | LEVOFLOXACIN EYE DROPS 5 mg/ml 4 TIMES PER DAY |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | 2 | 15FEB2018 | Dosage Unit Frequency | 1 drop ONCE |
| 100217 | DROP | Female | 72 | 1 | 02MAR2018 | Name Dosage Unit Frequency | LEVOFLOXACIN EYE DROPS 5 mg/ml 4 TIMES PER DAY |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | 2 | 08MAR2018 | Dosage Unit Frequency | 1 drop ONCE |
| 100218 | DROP | Male | 72 | 1 | 02MAR2018 | Name Dosage Unit Frequency | LEVOFLOXACIN EYE DROPS 5 mg/ml 4 TIMES PER DAY |
| | . | . | . | . | | TROPICAMIDE 100 MG/ML+ FENILEFRINA 5 MG/ L | |
| | . | . | . | 2 | 08MAR2018 | Dosage Unit Frequency | 1 drop ONCE |

Listing 9 (18 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|----------------|---------------------------|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100219 | GEL | Female | 83 | 1 | 09MAR2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | MG/ML |
| . | . | . | . | 2 | 15MAR2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | DROP |
| . | . | . | . | . | . | Frequency | ONCE |
| 100220 | GEL | Male | 64 | 1 | 09MAR2018 | Name | LEVOFLOXACIN EYEDROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | MG/ML |
| . | . | . | . | 2 | 15MAR2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | DROP |
| . | . | . | . | . | . | Frequency | ONCE |
| 100221 | GEL | Female | 76 | 1 | 30MAR2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | MG/ML |
| . | . | . | . | 2 | 05APR2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | DROP |
| . | . | . | . | . | . | Frequency | ONCE |
| 100222 | DROP | Female | 76 | 1 | 05APR2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | MG/ML |
| . | . | . | . | 2 | 12APR2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | DROP |
| . | . | . | . | . | . | Frequency | ONCE |

Listing 9 (19 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|----------------|---------------------------|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100223 | DROP | Male | 61 | 1 | 05APR2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | MG/ML |
| . | . | . | . | 2 | 12APR2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | DROP |
| . | . | . | . | . | . | Frequency | ONCE |
| 100224 | GEL | Female | 75 | 1 | 20APR2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | mg/ml |
| . | . | . | . | 2 | 26APR2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | drop |
| . | . | . | . | . | . | Frequency | ONCE |
| 100225 | DROP | Female | 79 | 1 | 20APR2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | mg/ml |
| . | . | . | . | 2 | 26APR2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | drop |
| . | . | . | . | . | . | Frequency | ONCE |
| 100226 | GEL | Female | 74 | 1 | 20APR2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | mg/ml |
| . | . | . | . | 2 | 26APR2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | drop |
| . | . | . | . | . | . | Frequency | ONCE |

Listing 9 (20 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|-------------------------------------|---|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100227 | DROP | Female | 68 | 1 | 27APR2018 | Name Dosage Unit Frequency | LEVOFLOXACIN EYE DROPS 5 mg/ml 4 TIMES PER DAY |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | 2 | 03MAY2018 | Dosage Unit Frequency | 1 drop ONCE |
| 100228 | GEL | Female | 68 | 1 | 27APR2018 | Name Dosage Unit Frequency | LEVOFLOXACIN EYE DROPS 5 mg/ml 4 TIMES PER DAY |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | 2 | 03MAY2018 | Dosage Unit Frequency | 1 drop ONCE |
| 100229 | GEL | Female | 70 | 1 | 04MAY2018 | Name Dosage Unit Frequency | LEVOFLOXACIN EYE DROPS 5 mg/ml 4 TIMES PER DAY |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | 2 | 10MAY2018 | Dosage Unit Frequency | 1 drop ONCE |
| 100230 | GEL | Female | 63 | 1 | 04MAY2018 | Name Dosage Unit Frequency | LEVOFLOXACIN EYE DROPS 5 mg/ml 4 TIMES PER DAY |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | 2 | 10MAY2018 | Dosage Unit Frequency | 1 drop ONCE |

Listing 9 (21 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|----------------|---------------------------|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100231 | DROP | Female | 74 | 1 | 04MAY2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | mg/ml |
| . | . | . | . | 2 | 10MAY2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | drop |
| . | . | . | . | . | . | Frequency | ONCE |
| 100232 | DROP | Female | 73 | 1 | 04MAY2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | mg/ml |
| . | . | . | . | 2 | 10MAY2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | drop |
| . | . | . | . | . | . | Frequency | ONCE |
| 100233 | GEL | Female | 72 | 1 | 18MAY2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | mg/ml |
| . | . | . | . | 2 | 24MAY2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | DROP |
| . | . | . | . | . | . | Frequency | ONCE |
| 100234 | GEL | Female | 73 | 1 | 18MAY2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | mg/ml |
| . | . | . | . | 2 | 24MAY2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | drop |
| . | . | . | . | . | . | Frequency | ONCE |

Listing 9 (22 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|----------------|---------------------------|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100235 | DROP | Male | 64 | 1 | 28MAY2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | mg/ml |
| . | . | . | . | 2 | 31MAY2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | drop |
| . | . | . | . | . | . | Frequency | ONCE |
| 100236 | DROP | Female | 70 | 1 | 28MAY2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | mg/ml |
| . | . | . | . | 2 | 31MAY2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | drop |
| . | . | . | . | . | . | Frequency | ONCE |
| 100237 | DROP | Male | 73 | 1 | 01JUN2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | mg/ml |
| . | . | . | . | 2 | 07JUN2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | drop |
| . | . | . | . | . | . | Frequency | ONCE |
| 100238 | GEL | Male | 78 | 1 | 01JUN2018 | Name | LEVOFLOXACIN EYE DROPS |
| . | . | . | . | . | . | Dosage | 5 |
| . | . | . | . | . | . | Unit | mg/ml |
| . | . | . | . | 2 | 07JUN2018 | Frequency | 4 TIMES PER DAY |
| . | . | . | . | . | . | Name | VISUMIDRIATIC FENILEFRINA |
| . | . | . | . | . | . | Dosage | 1 |
| . | . | . | . | . | . | Unit | drop |
| . | . | . | . | . | . | Frequency | ONCE |

Listing 9 (23 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|-------------------------------------|--|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100239 | DROP | Female | 80 | 1 | 08JUN2018 | Name Dosage Unit Frequency | LEVOFLOXACIN EYE DROPS 5 m 4 TIMES PER DAY |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | 2 | 14JUN2018 | Name Dosage Unit Frequency | |
| | . | . | . | . | | 1 drop ONCE | |
| 100241 | GEL | Female | 74 | 1 | 23OCT2018 | Name Dosage Unit Frequency | LEVOFLOXACINA 4 DROPTS 500mg DAILY |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | 2 | 25OCT2018 | Name Dosage Unit Frequency | |
| | . | . | . | . | | 5 mg DAILY | |
| 100242 | GEL | Female | 67 | 1 | 31OCT2018 | Name Dosage Unit Frequency | LEVOFLOXACIN 0.5% EYE DROP 1 drop EVERY 4 HOURS |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | 2 | 08NOV2018 | Name Dosage Unit Frequency | |
| | . | . | . | . | | 1 drop ONCE | |
| 100243 | DROP | Male | 74 | 1 | 30NOV2018 | Name Dosage Unit Frequency | LEVOFLOXACIN 0.5% EYE DROP 1 drop EVERY 4 HOURS |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | 2 | 06DEC2018 | Name Dosage Unit Frequency | |
| | . | . | . | . | | 1 drop ONCE | |

Listing 9 (24 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|-------------------------------------|--|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100244 | GEL | Female | 66 | 1 | 07DEC2018 | Name Dosage Unit Frequency | LEVOFLOXACIN 0.5% EYE DROP 1 drop 4 TIMES PER DAY |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | 2 | 13DEC2018 | Dosage Unit Frequency | 1 drop ONCE |
| 100245 | DROP | Female | 69 | 1 | 07DEC2018 | Name Dosage Unit Frequency | LEVOFLOXACIN 5MG/ML 1 DROP 4 TIMES PER DAY |
| | . | . | . | . | | VISUMIDRIATIC FENILEFRINA | |
| | . | . | . | 2 | 13DEC2018 | Dosage Unit Frequency | 1 DROP ONCE |
| 100303 | DROP | Female | 73 | 2 | 02NOV2017 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 100+5 mg/ml ONCE |
| | . | . | . | . | | | |
| 100304 | DROP | Male | 58 | 2 | 16NOV2017 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 100+5 mg/ml ONCE |
| | . | . | . | . | | | |
| 100305 | DROP | Female | 85 | 2 | 16NOV2017 | Name Dosage Unit Frequency | VISUMIDRIATC FENILEFRINA 100+5 mg/ml ONCE |
| | . | . | . | . | | | |
| 100306 | DROP | Female | 84 | 2 | 22NOV2017 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 100/50 mg/ml ONCE |
| | . | . | . | . | | | |
| 100307 | GEL | Female | 73 | 2 | 29NOV2017 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 100/5 mg/ml ONCE |
| | . | . | . | . | | | |

Listing 9 (25 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | |
|-------------|---------------|---------------|-----|-----------|--|---------------------------|
| Sbj Code | Study drug | Age (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100308 | GEL | Female 85 | 2 | 29NOV2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | |
| 100309 | DROP | Female 61 | 2 | 29NOV2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | |
| 100310 | GEL | Female 73 | 2 | 30NOV2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | |
| 100311 | GEL | Female 83 | 2 | 05DEC2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | |
| 100312 | DROP | Female 71 | 2 | 05DEC2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | |
| 100313 | GEL | Male 71 | 2 | 04DEC2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit ml/mg Frequency ONCE | |
| 100314 | DROP | Male 67 | 2 | 05DEC2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit ml/mg Frequency ONCE | |
| 100315 | GEL | Female 65 | 2 | 05DEC2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit ml/mg Frequency ONCE | |

Listing 9 (26 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|-------------|---------------|---------------|--------------|-------------|--|---------------------------|--|
| Sbj Code | Study drug | Age (year) | ----- No. | Date | Mydriatic drug | Antibiotic before surgery | |
| 100316 | DROP | Male | 76 | 2 05DEC2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit ml/mg Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100317 | GEL | Male | 85 | 2 05DEC2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100318 | GEL | Female | 80 | 2 05DEC2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100319 | DROP | Male | 70 | 2 05DEC2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100320 | DROP | Male | 69 | 2 05DEC2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100321 | GEL | Male | 72 | 2 11DEC2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100322 | GEL | Male | 80 | 2 13DEC2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100323 | DROP | Female | 76 | 2 13DEC2017 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |

Listing 9 (27 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | | | |
|-------------|---------------|---------------|--------------|-------------|--------------------------------|---------------------------|--|--|--|
| Sbj Code | Study drug | Age (year) | ----- No. | Date | Mydriatic drug | Antibiotic before surgery | | | |
| 100324 | DROP | Male | 65 | 2 18DEC2017 | Name VISUMIDRIATIC FENILEFRINA | | | | |
| . | . | . | . | . | Dosage 100/5 | | | | |
| . | . | . | . | . | Unit mg/ml | | | | |
| . | . | . | . | . | Frequency ONCE | | | | |
| 100325 | GEL | Female | 83 | 2 18DEC2017 | Name VISUMIDRIATIC FENILEFRINA | | | | |
| . | . | . | . | . | Dosage 100/5 | | | | |
| . | . | . | . | . | Unit mg/ml | | | | |
| . | . | . | . | . | Frequency ONCE | | | | |
| 100326 | DROP | Male | 81 | 2 18DEC2017 | Name VISUMIDRIATIC FENILEFRINA | | | | |
| . | . | . | . | . | Dosage 100/5 | | | | |
| . | . | . | . | . | Unit mg/ml | | | | |
| . | . | . | . | . | Frequency ONCE | | | | |
| 100327 | GEL | Female | 73 | 2 18DEC2017 | Name VISUMIDRIATIC FENILEFRINA | | | | |
| . | . | . | . | . | Dosage 100/5 | | | | |
| . | . | . | . | . | Unit mg/ml | | | | |
| . | . | . | . | . | Frequency ONCE | | | | |
| 100328 | DROP | Male | 82 | 2 18DEC2017 | Name VISUMIDRIATIC FENILEFRINA | | | | |
| . | . | . | . | . | Dosage 100/5 | | | | |
| . | . | . | . | . | Unit mg/ml | | | | |
| . | . | . | . | . | Frequency ONCE | | | | |
| 100329 | GEL | Male | 74 | 2 18DEC2017 | Name VISUMIDRIATIC FENILEFRINA | | | | |
| . | . | . | . | . | Dosage 100/5 | | | | |
| . | . | . | . | . | Unit mg/ml | | | | |
| . | . | . | . | . | Frequency ONCE | | | | |
| 100330 | DROP | Male | 61 | 2 19DEC2017 | Name VISUMIDRIATIC FENILEFRINA | | | | |
| . | . | . | . | . | Dosage 100/5 | | | | |
| . | . | . | . | . | Unit mg/ml | | | | |
| . | . | . | . | . | Frequency ONCE | | | | |
| 100331 | GEL | Female | 71 | 2 19DEC2017 | Name VISUMIDRIATIC FENILEFRINA | | | | |
| . | . | . | . | . | Dosage 100/5 | | | | |
| . | . | . | . | . | Unit mg/ml | | | | |
| . | . | . | . | . | Frequency ONCE | | | | |

Listing 9 (28 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|-------------|---------------|---------------|-----|------|----------------|-------------------------------------|---|
| Sbj Code | Study drug | Age (year) | No. | Date | Mydriatic drug | Antibiotic before surgery | |
| 100332 | DROP | Male | 82 | 2 | 12JAN2018 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 100/5 mg/ml ONCE |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100333 | DROP | Male | 62 | 2 | 25JAN2018 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 100/5 mg/ml ONCE |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100334 | GEL | Male | 72 | 2 | 24JAN2018 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 100/5 mg/ml ONCE |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100335 | DROP | Female | 80 | 2 | 06FEB2018 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 100/5 mg/ml ONCE |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100336 | GEL | Female | 82 | 2 | 06MAR2018 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 100/5 mg/ml ONCE |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100337 | GEL | Male | 72 | 2 | 16MAR2018 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 100/5 mg/ml ONCE |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100338 | DROP | Female | 87 | 2 | 21MAR2018 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 100/5 mg/ml ONCE |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100339 | GEL | Male | 56 | 2 | 28MAR2018 | Name Dosage Unit Frequency | VISUMIDRIATIC FENILEFRINA 100/5 mg/ml ONCE |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |

Listing 9 (29 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | | | |
|--------|-------|--------|--------|-----|-----------|----------------|---------------------------|---------------------------|--|
| Sbj | Study | Age | ----- | | | Mydriatic drug | | Antibiotic before surgery | |
| Code | drug | Sex | (year) | No. | Date | | | | |
| 100340 | DROP | Male | 83 | 2 | 12APR2018 | Name | VISUMIDRIATIC FENILEFRINA | | |
| . | . | . | . | . | | Dosage | 100/5 | | |
| . | . | . | . | . | | Unit | ml/mg | | |
| . | . | . | . | . | | Frequency | ONCE | | |
| 100341 | GEL | Male | 88 | 2 | 12APR2018 | Name | VISUMIDRIATIC FENILEFRINA | | |
| . | . | . | . | . | | Dosage | 100/5 | | |
| . | . | . | . | . | | Unit | ml/mg | | |
| . | . | . | . | . | | Frequency | ONCE | | |
| 100342 | DROP | Female | 86 | 2 | 12APR2018 | Name | VISUMIDRIATIC FENILEFRINA | | |
| . | . | . | . | . | | Dosage | 100/5 | | |
| . | . | . | . | . | | Unit | ml/mg | | |
| . | . | . | . | . | | Frequency | ONCE | | |
| 100343 | GEL | Male | 74 | 2 | 10APR2018 | Name | VISUMIDRIATIC FENILEFRINA | | |
| . | . | . | . | . | | Dosage | 100/5 | | |
| . | . | . | . | . | | Unit | ml/mg | | |
| . | . | . | . | . | | Frequency | ONCE | | |
| 100344 | DROP | Female | 68 | 2 | 10APR2018 | Name | VISUMIDRIATIC FENILEFRINA | | |
| . | . | . | . | . | | Dosage | 100/5 | | |
| . | . | . | . | . | | Unit | mg/ml | | |
| . | . | . | . | . | | Frequency | ONCE | | |
| 100345 | GEL | Male | 48 | 2 | 10APR2018 | Name | VISUMIDRIATIC FENILEFRINA | | |
| . | . | . | . | . | | Dosage | 100/5 | | |
| . | . | . | . | . | | Unit | mg/ml | | |
| . | . | . | . | . | | Frequency | ONCE | | |
| 100346 | DROP | Female | 77 | 2 | 12APR2018 | Name | VISUMIDRIATIC FENILEFRINA | | |
| . | . | . | . | . | | Dosage | 100/5 | | |
| . | . | . | . | . | | Unit | mg/ml | | |
| . | . | . | . | . | | Frequency | ONCE | | |
| 100347 | GEL | Male | 58 | 2 | 18APR2018 | Name | VISUMIDRIATIC FENILEFRINA | | |
| . | . | . | . | . | | Dosage | 100/5 | | |
| . | . | . | . | . | | Unit | mg/ml | | |
| . | . | . | . | . | | Frequency | ONCE | | |

Listing 9 (30 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|-------------|---------------|---------------|-----|-----------|--|---------------------------|--|
| Sbj Code | Study drug | Age (year) | No. | Date | Mydriatic drug | Antibiotic before surgery | |
| 100348 | GEL | Female 38 | 2 | 24APR2018 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100349 | DROP | Male 71 | 2 | 24MAY2018 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100350 | DROP | Female 67 | 2 | 22MAY2018 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100351 | GEL | Female 79 | 2 | 25MAY2018 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100352 | DROP | Female 63 | 2 | 29MAY2018 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/mg Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100353 | GEL | Female 72 | 2 | 07JUN2018 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100354 | GEL | Female 80 | 2 | 07JUN2018 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| 100355 | DROP | Female 80 | 2 | 13JUN2018 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |
| . | . | . | . | . | | | |

Listing 9 (31 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | | |
|--------|-------|--------|--------|-----|-----------|---|---------------------------|
| Sbj | Study | Age | ----- | | | | |
| Code | drug | Sex | (year) | No. | Date | Mydriatic drug | Antibiotic before surgery |
| 100356 | GEL | Male | 74 | 2 | 18JUN2018 | Name VISUMIDRIATIC FENILEFRINA Dosage 100/5 Unit mg/ml Frequency ONCE | |
| 200101 | GEL | Female | 66 | 2 | 16JAN2018 | Name PHENYLEPHRIN-TROPICAMID Dosage 3 Unit Drops Frequency ONCE Name ADRENALIN 0,05% Dosage 1 Unit ml Frequency ONCE | |
| 200102 | DROP | Female | 76 | 2 | 30JAN2018 | Name ADRENALIN 0,05% Dosage 1 Unit ml Frequency ONCE Name PHENYLEPHRIN-TROPICAMID Dosage 2 Unit Drops Frequency ONCE | |
| 200103 | DROP | Male | 82 | 2 | 13FEB2018 | Name ADRENALIN 0,05% Dosage 1 Unit ml Frequency ONCE Name PHENYLEPHRIN-TROPICAMID Dosage 2 Unit drops Frequency ONCE | |
| 200104 | GEL | Female | 78 | 2 | 08MAY2018 | Name ADRENALIN 0,05% Dosage 1 Unit ml Frequency ONCE Name PHENYLEPHRIN-TROPICAMID Dosage 3 Unit drops Frequency ONCE | |

Listing 9 (32 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | |
|--------|-------|--------|--------|-----|-----------|------------------------------|
| Sbj | Study | Age | ----- | | | |
| Code | drug | Sex | (year) | No. | Date | |
| 200105 | GEL | Female | 65 | 2 | 29MAY2018 | Mydriatic drug |
| . | . | . | . | . | | Name ADRENALIN 0,05% |
| . | . | . | . | . | | Dosage 1 |
| . | . | . | . | . | | Unit ml |
| . | . | . | . | 2 | 29MAY2018 | Frequency ONCE |
| . | . | . | . | . | | Name PHENYLEPHRIN TROPICAMID |
| . | . | . | . | . | | Dosage 3 |
| . | . | . | . | . | | Unit Drops |
| . | . | . | . | . | | Frequency ONCE |
| 200106 | DROP | Female | 75 | 2 | 26JUN2018 | Antibiotic before surgery |
| . | . | . | . | . | | Name ADRENALIN 0,05% |
| . | . | . | . | . | | Dosage 1 |
| . | . | . | . | . | | Unit ml |
| . | . | . | . | . | | Frequency ONCE |
| . | . | . | . | 2 | 26JUN2018 | Name PHENYLEPHRIN-TROPICAMID |
| . | . | . | . | . | | Dosage 3 |
| . | . | . | . | . | | Unit Drops |
| . | . | . | . | . | | Frequency ONCE |
| 200107 | DROP | Female | 54 | 2 | 03JUL2018 | Mydriatic drug |
| . | . | . | . | . | | Name ADRENALIN 0,05% |
| . | . | . | . | . | | Dosage 1 |
| . | . | . | . | . | | Unit ml |
| . | . | . | . | . | | Frequency ONCE |
| . | . | . | . | 2 | 03JUL2018 | Name PHENYPEPHRIN-TROPICAMID |
| . | . | . | . | . | | Dosage 3 |
| . | . | . | . | . | | Unit Drops |
| . | . | . | . | . | | Frequency ONCE |
| 200108 | GEL | Male | 77 | 2 | 04SEP2018 | Antibiotic before surgery |
| . | . | . | . | . | | Name ADRENALIN 0,05% |
| . | . | . | . | . | | Dosage 1 |
| . | . | . | . | . | | Unit ml |
| . | . | . | . | . | | Frequency ONCE |
| . | . | . | . | 2 | 04SEP2018 | Name PHENYLEPHRIN-TROPICAMID |
| . | . | . | . | . | | Dosage 2 |
| . | . | . | . | . | | Unit Drops |
| . | . | . | . | . | | Frequency ONCE |

Listing 9 (33 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | |
|--------|-------|--------|--------|-----|-----------|------------------------------|
| Sbj | Study | Age | ----- | | | |
| Code | drug | Sex | (year) | No. | Date | |
| 200109 | GEL | Female | 84 | 2 | 02OCT2018 | Mydriatic drug |
| . | . | . | . | . | | Name ADRENALIN 0,05% |
| . | . | . | . | . | | Dosage 1 |
| . | . | . | . | . | | Unit ml |
| . | . | . | . | 2 | 02OCT2018 | Frequency ONCE |
| . | . | . | . | . | | Name PHENYLEPHRIN-TROPICAMID |
| . | . | . | . | . | | Dosage 2 |
| . | . | . | . | . | | Unit Drops |
| . | . | . | . | . | | Frequency ONCE |
| 200110 | DROP | Male | 64 | 2 | 09OCT2018 | Antibiotic before surgery |
| . | . | . | . | . | | Name ADRENALIN 0,05% |
| . | . | . | . | . | | Dosage 1 |
| . | . | . | . | . | | Unit ml |
| . | . | . | . | 2 | 09OCT2018 | Frequency ONCE |
| . | . | . | . | . | | Name PHENYLEPHRIN-TROPICAMID |
| . | . | . | . | . | | Dosage 2 |
| . | . | . | . | . | | Unit Dropa |
| . | . | . | . | . | | Frequency ONCE |
| 200111 | GEL | Male | 73 | 2 | 06NOV2018 | |
| . | . | . | . | . | | Name ADRENALIN |
| . | . | . | . | . | | Dosage 1 |
| . | . | . | . | . | | Unit ml |
| . | . | . | . | 2 | 06NOV2018 | Frequency ONCE |
| . | . | . | . | . | | Name PHENYLEPHRIN-TROPICAMID |
| . | . | . | . | . | | Dosage 2 |
| . | . | . | . | . | | Unit Drop |
| . | . | . | . | . | | Frequency ONCE |
| 200112 | DROP | Male | 85 | 2 | 13NOV2018 | |
| . | . | . | . | . | | Name ADRENALIN 0,05% |
| . | . | . | . | . | | Dosage 1 |
| . | . | . | . | . | | Unit ml |
| . | . | . | . | 2 | 13NOV2018 | Frequency ONCE |
| . | . | . | . | . | | Name PHENYLEPHRIN-TROPICAMID |
| . | . | . | . | . | | Dosage 2 |
| . | . | . | . | . | | Unit Drops |
| . | . | . | . | . | | Frequency ONCE |

Listing 9 (34 of 35): Mydriatic drugs and Antibiotic treatments before surgery

| Visit | | | | | | |
|--------|-------|--------|--------|-----------|-----------|------------------------------|
| Sbj | Study | Age | ----- | | | |
| Code | drug | Sex | (year) | No. | Date | |
| 200113 | DROP | Male | 77 | 2 | 13NOV2018 | Mydriatic drug |
| . | . | . | . | . | | Name ADRENALIN 0,05% |
| . | . | . | . | . | | Dosage 1 |
| . | . | . | . | . | | Unit ml |
| . | . | . | 2 | 13NOV2018 | | Frequency ONCE |
| . | . | . | . | . | | Name PHENYLEPHRIN-TROPICAMID |
| . | . | . | . | . | | Dosage 2 |
| . | . | . | . | . | | Unit Drops |
| . | . | . | . | . | | Frequency ONCE |
| 200114 | DROP | Female | 64 | 2 | 27NOV2018 | Antibiotic before surgery |
| . | . | . | . | . | | Name ADRENALIN 0,05% |
| . | . | . | . | . | | Dosage 1 |
| . | . | . | . | . | | Unit ml |
| . | . | . | 2 | 27NOV2018 | | Frequency ONCE |
| . | . | . | . | . | | Name PHENYLEPHRIN-TROPICAMID |
| . | . | . | . | . | | Dosage 2 |
| . | . | . | . | . | | Unit drops |
| . | . | . | . | . | | Frequency ONCE |
| 200115 | GEL | Female | 70 | 2 | 18DEC2018 | Name ADRENALIN |
| . | . | . | . | . | | Dosage 1 |
| . | . | . | . | . | | Unit ml |
| . | . | . | 2 | 18DEC2018 | | Frequency ONCE |
| . | . | . | . | . | | Name PHENYLEPHRIN-TROPICAMID |
| . | . | . | . | . | | Dosage 2 |
| . | . | . | . | . | | Unit drops |
| . | . | . | . | . | | Frequency ONCE |
| 200202 | DROP | Female | 71 | 2 | 18JUN2018 | Name MYDRUM (TROPICAMIDE) |
| . | . | . | . | . | | Dosage 5MG TROPICAMIDE/1ML |
| . | . | . | . | . | | Unit drop |
| . | . | . | . | . | | Frequency UNKNOWN |
| 200203 | GEL | Male | 66 | 2 | 26JUN2018 | Name MYDRUM (TROPICAMIDE) |
| . | . | . | . | . | | Dosage 5MG TROPICAMIDE/1ML |
| . | . | . | . | . | | Unit drop |
| . | . | . | . | . | | Frequency UNKNOWN |

Listing 9 (35 of 35): Mydriatic drugs and Antibiotic treatments before surgery

=====

Visit

| Sbj | Study | Age | ----- | | | | |
|--------|-------|------|--------|-----|-----------|-----------|----------------------|
| Code | drug | Sex | (year) | No. | Date | | |
| 200204 | GEL | Male | 58 | 2 | 03JUL2018 | Name | MYDRUM (TROPICAMIDE) |
| . | . | . | . | . | | Dosage | 5MG TROPICAMIDE/1ML |
| . | . | . | . | . | | Unit | drop |
| . | . | . | . | . | | Frequency | UNKNOWN |

=====

SAS program: L03_List_09.sas - SAS dataset name(s): RAND,DEMOGRAPHY,MYDRIATIC_COD,ANTI_BEFORE_COD

Listing 10 (1 of 3): Antibiotic treatments after surgery

| Sbj Code | Study drug | Age (year) | Visit No. | Antibiotic after surgery | | | | |
|-------------|---------------|---------------|--------------|--------------------------|-------------------------|-------------------|--------|-----------|
| | | | | Date | Name | Dosage | Unit | Frequency |
| 100201 | GEL | Female 80 | 1 | 01DEC2017 | CEFUROXIME | 1 MG/100mg/microl | ONCE | |
| 100202 | DROP | Female 70 | 1 | 01DEC2017 | APROKAM 1 MG/0.1ML | 0.1 | mL | ONCE |
| 100203 | DROP | Female 76 | 1 | 07DEC2017 | APROKAM 1 MG/0.1ML | 0.1 | mL | ONCE |
| 100204 | GEL | Male 71 | 1 | 07DEC2017 | APROKAM 1 MG /0.1 ML | 0.1 | ml | ONCE |
| 100205 | GEL | Male 75 | 1 | 14DEC2017 | APROKAM 1MG/0.1ML | 0.1 | ML | ONCE |
| 100206 | DROP | Female 81 | 1 | 05JAN2018 | APROKAM 1 MG /0.1 ML | 0.1 | ml | ONCE |
| 100207 | DROP | Female 65 | 1 | 05JAN2018 | APROKAM 1 MG/0.1 ML | 0.1 | ml | ONCE |
| 100208 | GEL | Female 79 | 1 | 05JAN2018 | APROKAM 1 MG/ML | 0.1 | ml | ONCE |
| 100213 | DROP | Female 81 | 1 | 25JAN2018 | APROKAM 1 MG/100 MICROL | 100 | microl | ONCE |
| 100214 | DROP | Female 77 | 1 | 05FEB2018 | APROKAM 1 MG /0.1 ML | 0.1 | ml | ONCE |
| 100215 | GEL | Female 83 | 1 | 05FEB2018 | APROKAM 1 MG /0.1 ML | 0.1 | ml | ONCE |
| 100216 | GEL | Female 74 | 1 | 09FEB2018 | APROKAM 1MG /0.1 ML | 0.1 | ml | ONCE |
| 100217 | DROP | Female 72 | 1 | 02MAR2018 | APROKAM 1 MG /0.1 ML | 0.1 | ml | ONCE |
| 100218 | DROP | Male 72 | 1 | 02MAR2018 | APROKAM 1 MG/0.1 ML | 0.1 | ml | ONCE |
| 100219 | GEL | Female 83 | 1 | 09MAR2018 | APROKAM 1MG/0.1 ML | 0.1 | ML | ONCE |
| 100220 | GEL | Male 64 | 1 | 09MAR2018 | APROKAM 1 MG/0.1 ML | 0.1 | ML | ONCE |
| 100221 | GEL | Female 76 | 1 | 30MAR2018 | APROKAM 1 MG/0.1 ML | 0.1 | ML | ONCE |
| 100222 | DROP | Female 76 | 1 | 05APR2018 | APROKAM 1 MG/0.1 ML | 0.1 | ML | ONCE |
| 100223 | DROP | Male 61 | 1 | 05APR2018 | APROKAM 1 MG/0.1 ML | 0.1 | ML | ONCE |
| 100224 | GEL | Female 75 | 1 | 20APR2018 | APROKAM 1 MG/0.1ML | 0.1 | ml | ONCE |

Listing 10 (2 of 3): Antibiotic treatments after surgery

| Sbj Code | Study drug | Age (year) | Visit No. | Antibiotic after surgery | | | | |
|-------------|---------------|---------------|--------------|--------------------------|------------------------|--------|--------|-----------|
| | | | | Date | Name | Dosage | Unit | Frequency |
| 100225 | DROP | Female 79 | 1 | 20APR2018 | APROKAM 1MG/0.1 ML | 0.1 | ml | ONCE |
| 100226 | GEL | Female 74 | 1 | 20APR2018 | APROKAM 1MG/0.1 ML | 0.1 | 0.1 ml | ONCE |
| 100227 | DROP | Female 68 | 1 | 27APR2018 | APROKAM 1MG/0.1 ML | 0.1 | ml | ONCE |
| 100228 | GEL | Female 68 | 1 | 27APR2018 | APROKAM 1MG/0.1 ML | 0.1 | ml | ONCE |
| 100229 | GEL | Female 70 | 1 | 04MAY2018 | APROKAM 1MG/0.1 ML | 0.1 | ml | ONCE |
| 100230 | GEL | Female 63 | 1 | 04MAY2018 | APROKAM 1MG/0.1 ML | 0.1 | ml | ONCE |
| 100231 | DROP | Female 74 | 1 | 04MAY2018 | APROKAM 1MG/0.1 ML | 0.1 | ml | ONCE |
| 100232 | DROP | Female 73 | 1 | 04MAY2018 | APROKAM 1MG/0.1 ML | 0.1 | 0.1 ml | ONCE |
| 100233 | GEL | Female 72 | 1 | 18MAY2018 | APROKAM 1 MG /0.1 ML | 0.1 | ML | ONCE |
| 100234 | GEL | Female 73 | 1 | 18MAY2018 | APROKAM 1 MG /0.1 ML | 0.1 | ml | ONCE |
| 100235 | DROP | Male 64 | 1 | 28MAY2018 | APROKAM 1 MG /0.1 ML | 0.1 | ml | ONCE |
| 100236 | DROP | Female 70 | 1 | 28MAY2018 | APROKAM 1 MG /0.1 ML | 0.1 | ml | ONCE |
| 100237 | DROP | Male 73 | 1 | 01JUN2018 | APROKAM 1 MG /0.1 ML | 0.1 | ml | ONCE |
| 100238 | GEL | Male 78 | 1 | 01JUN2018 | APROKAM 1 MG /0.1 ML | 0.1 | ml | ONCE |
| 100239 | DROP | Female 80 | 1 | 08JUN2018 | APROKAM 1 MG /0.1 ML | 0.1 | ml | ONCE |
| 100242 | GEL | Female 67 | 1 | 31OCT2018 | APROKAM 1MG/100 MICROL | 100 | microl | ONCE |
| 100243 | DROP | Male 74 | 1 | 30NOV2018 | APROKAM 1MG/100 MICROL | 100 | microl | ONCE |
| 100244 | GEL | Female 66 | 1 | 07DEC2018 | APROKAM 1MG/100 MICROL | 100 | microl | ONCE |
| 100245 | DROP | Female 69 | 1 | 07DEC2018 | APROKAM 1 MG/0,1 ML | 0,1 | ML | ONCE |
| 100304 | DROP | Male 58 | 1 | 10NOV2017 | APROKAM | # | # | ONCE |

Listing 10 (3 of 3): Antibiotic treatments after surgery

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=====
          Visit           Antibiotic after surgery
Sbj   Study    Age  -----
Code   drug     Sex (year) No. Date      Name        Dosage Unit   Frequency
=====
200103 DROP   Male   82     1  12FEB2018 CEFUROXIM   1       ml      ONCE
=====
```

SAS program: L03_List_10.sas - SAS dataset name(s): RAND,DEMOGRAPHY,ANTI_AFTER_COD

Listing 11 (1 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit | Study Treatment |
|-------------|---------------|---------------|-------|-----------------|
| | | | No. | Date |
| 100101 | DROP | Female 84 | 2 | 25OCT2017 Yes |
| . | . | . | 3 | 26OCT2017 Yes |
| . | . | . | 4 | 02NOV2017 Yes |
| 100102 | GEL | Male 80 | 2 | 31OCT2017 Yes |
| . | . | . | 3 | 01NOV2017 Yes |
| . | . | . | 4 | 07NOV2017 Yes |
| 100104 | GEL | Male 70 | 2 | 07NOV2017 Yes |
| . | . | . | 3 | 08NOV2017 Yes |
| . | . | . | 4 | 14NOV2017 Yes |
| 100105 | DROP | Female 85 | 2 | 08NOV2017 Yes |
| . | . | . | 3 | 09NOV2017 Yes |
| . | . | . | 4 | 15NOV2017 Yes |
| 100106 | GEL | Male 56 | 2 | 15NOV2017 Yes |
| . | . | . | 3 | 16NOV2017 Yes |
| . | . | . | 4 | 22NOV2017 Yes |
| 100107 | DROP | Female 82 | 2 | 28NOV2017 Yes |
| . | . | . | 3 | 29NOV2017 Yes |
| . | . | . | 4 | 05DEC2017 Yes |
| 100108 | DROP | Female 73 | 2 | 06DEC2017 Yes |
| . | . | . | 3 | 07DEC2017 Yes |
| . | . | . | 4 | 13DEC2017 Yes |
| 100109 | GEL | Female 56 | 2 | 12DEC2017 Yes |
| . | . | . | 3 | 13DEC2017 Yes |
| . | . | . | 4 | 19DEC2017 Yes |
| 100110 | DROP | Female 75 | 2 | 13DEC2017 Yes |
| . | . | . | 3 | 14DEC2017 Yes |
| . | . | . | 4 | 20DEC2017 Yes |
| 100111 | DROP | Female 60 | 2 | 13DEC2017 Yes |
| . | . | . | 3 | 14DEC2017 Yes |
| . | . | . | 4 | 20DEC2017 Yes |

Listing 11 (2 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Study Treatment | |
|-------------|---------------|---------------|--------------|-----------------|-------------------------------|
| | | | | Date | administered after surgery |
| 100112 | GEL | Male 73 | 2 | 03JAN2018 | Yes |
| . | . | . | 3 | 04JAN2018 | Yes |
| . | . | . | 4 | 10JAN2018 | Yes |
| 100113 | GEL | Female 77 | 2 | 03JAN2018 | Yes |
| . | . | . | 3 | 04JAN2018 | Yes |
| . | . | . | 4 | 10JAN2018 | Yes |
| 100114 | GEL | Male 64 | 2 | 03JAN2018 | Yes |
| . | . | . | 3 | 04JAN2018 | Yes |
| . | . | . | 4 | 10JAN2018 | Yes |
| 100115 | DROP | Male 76 | 2 | 04JAN2018 | Yes |
| . | . | . | 3 | 05JAN2018 | Yes |
| . | . | . | 4 | 11JAN2018 | Yes |
| 100116 | GEL | Male 62 | 2 | 04JAN2018 | Yes |
| . | . | . | 3 | 05JAN2018 | Yes |
| . | . | . | 4 | 11JAN2018 | Yes |
| 100117 | DROP | Female 51 | 2 | 10JAN2018 | Yes |
| . | . | . | 3 | 11JAN2018 | Yes |
| . | . | . | 4 | 17JAN2018 | Yes |
| 100118 | DROP | Female 78 | 2 | 17JAN2018 | Yes |
| . | . | . | 3 | 18JAN2018 | Yes |
| . | . | . | 4 | 24JAN2018 | Yes |
| 100119 | DROP | Female 72 | 2 | 24JAN2018 | Yes |
| . | . | . | 3 | 25JAN2018 | Yes |
| . | . | . | 4 | 31JAN2018 | Yes |
| 100120 | GEL | Male 79 | 2 | 24JAN2018 | Yes |
| . | . | . | 3 | 25JAN2018 | Yes |
| . | . | . | 4 | 31JAN2018 | Yes |
| 100121 | GEL | Male 80 | 2 | 24JAN2018 | Yes |
| . | . | . | 3 | 25JAN2018 | Yes |
| . | . | . | 4 | 31JAN2018 | Yes |

Listing 11 (3 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit | Study Treatment |
|-------------|---------------|---------------|-------|-----------------|
| | | | No. | Date |
| 100122 | DROP | Female 76 | 2 | 25JAN2018 Yes |
| . | . | . | 3 | 26JAN2018 Yes |
| . | . | . | 4 | 01FEB2018 Yes |
| 100123 | DROP | Female 76 | 2 | 25JAN2018 Yes |
| . | . | . | 3 | 26JAN2018 Yes |
| . | . | . | 4 | 01FEB2018 Yes |
| 100124 | GEL | Female 71 | 2 | 01FEB2018 Yes |
| . | . | . | 3 | 02FEB2018 Yes |
| . | . | . | 4 | 08FEB2018 Yes |
| 100125 | GEL | Female 62 | 2 | 01FEB2018 Yes |
| . | . | . | 3 | 02FEB2018 Yes |
| . | . | . | 4 | 08FEB2018 Yes |
| 100126 | GEL | Female 85 | 2 | 07FEB2018 Yes |
| . | . | . | 3 | 08FEB2018 Yes |
| . | . | . | 4 | 14FEB2018 Yes |
| 100127 | GEL | Female 68 | 2 | 08FEB2018 Yes |
| . | . | . | 3 | 09FEB2018 Yes |
| . | . | . | 4 | 15FEB2018 Yes |
| 100128 | DROP | Male 80 | 2 | 08FEB2018 Yes |
| . | . | . | 3 | 09FEB2018 Yes |
| . | . | . | 4 | 15FEB2018 Yes |
| 100129 | DROP | Female 78 | 2 | 08FEB2018 Yes |
| . | . | . | 3 | 09FEB2018 Yes |
| . | . | . | 4 | 15FEB2018 Yes |
| 100130 | GEL | Male 66 | 2 | 21FEB2018 Yes |
| . | . | . | 3 | 22FEB2018 Yes |
| . | . | . | 4 | 28FEB2018 Yes |
| 100131 | DROP | Female 77 | 2 | 21FEB2018 Yes |
| . | . | . | 3 | 22FEB2018 Yes |
| . | . | . | 4 | 28FEB2018 Yes |

Listing 11 (4 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Study Treatment administered after surgery | |
|-------------|---------------|---------------|--------------|--|-----|
| | | | | Date | |
| 100132 | DROP | Male 69 | 2 | 07MAR2018 | Yes |
| . | . | . | 3 | 08MAR2018 | Yes |
| . | . | . | 4 | 14MAR2018 | Yes |
| 100133 | GEL | Male 74 | 2 | 07MAR2018 | Yes |
| . | . | . | 3 | 08MAR2018 | Yes |
| . | . | . | 4 | 14MAR2018 | Yes |
| 100134 | DROP | Female 66 | 2 | 07MAR2018 | Yes |
| . | . | . | 3 | 08MAR2018 | Yes |
| . | . | . | 4 | 14MAR2018 | Yes |
| 100135 | GEL | Male 69 | 2 | 15MAR2018 | Yes |
| . | . | . | 3 | 16MAR2018 | Yes |
| . | . | . | 4 | 22MAR2018 | Yes |
| 100136 | GEL | Female 90 | 2 | 05APR2018 | Yes |
| . | . | . | 3 | 06APR2018 | Yes |
| . | . | . | 4 | 12APR2018 | Yes |
| 100137 | DROP | Female 62 | 2 | 19APR2018 | Yes |
| . | . | . | 3 | 20APR2018 | Yes |
| . | . | . | 4 | 26APR2018 | Yes |
| 100138 | GEL | Male 63 | 2 | 19APR2018 | Yes |
| . | . | . | 3 | 20APR2018 | Yes |
| . | . | . | 4 | 26APR2018 | Yes |
| 100139 | DROP | Female 71 | 2 | 26APR2018 | Yes |
| . | . | . | 3 | 27APR2018 | Yes |
| . | . | . | 4 | 03MAY2018 | Yes |
| 100140 | GEL | Male 81 | 2 | 02MAY2018 | Yes |
| . | . | . | 3 | 03MAY2018 | Yes |
| . | . | . | 4 | 09MAY2018 | Yes |
| 100141 | DROP | Female 74 | 2 | 02MAY2018 | Yes |
| . | . | . | 3 | 03MAY2018 | Yes |
| . | . | . | 4 | 10MAY2018 | Yes |

Listing 11 (5 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visit | Study Treatment |
|-------------|---------------|---------------|--------------|-----------|-------------------------------|
| | | | | Date | administered after surgery |
| 100142 | GEL | Female 77 | 2 | 16MAY2018 | Yes |
| . | . | . | 3 | 17MAY2018 | Yes |
| . | . | . | 4 | 23MAY2018 | Yes |
| 100143 | GEL | Male 74 | 2 | 20JUN2018 | Yes |
| . | . | . | 3 | 21JUN2018 | Yes |
| . | . | . | 4 | 27JUN2018 | Yes |
| 100144 | DROP | Female 89 | 2 | 27JUN2018 | Yes |
| . | . | . | 3 | 28JUN2018 | Yes |
| . | . | . | 4 | 04JUL2018 | Yes |
| 100145 | GEL | Male 81 | 2 | 04JUL2018 | Yes |
| . | . | . | 3 | 05JUL2018 | Yes |
| . | . | . | 4 | 11JUL2018 | Yes |
| 100146 | GEL | Male 71 | 2 | 21AUG2018 | Yes |
| . | . | . | 3 | 22AUG2018 | Yes |
| . | . | . | 4 | 29AUG2018 | Yes |
| 100147 | DROP | Male 48 | 2 | 28AUG2018 | Yes |
| . | . | . | 3 | 29AUG2018 | No |
| . | . | . | 4 | 20SEP2018 | Yes |
| 100148 | DROP | Female 83 | 2 | 30AUG2018 | Yes |
| . | . | . | 3 | 31AUG2018 | Yes |
| . | . | . | 4 | 06SEP2018 | Yes |
| 100149 | DROP | Female 71 | 2 | 30AUG2018 | Yes |
| . | . | . | 3 | 31AUG2018 | Yes |
| . | . | . | 4 | 06SEP2018 | Yes |
| 100150 | GEL | Female 77 | 2 | 05SEP2018 | Yes |
| . | . | . | 3 | 06SEP2018 | Yes |
| . | . | . | 4 | 12SEP2018 | Yes |
| 100151 | DROP | Female 67 | 2 | 04OCT2018 | Yes |
| . | . | . | 3 | 05OCT2018 | Yes |
| . | . | . | 4 | 12OCT2018 | Yes |

Listing 11 (6 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit | Study Treatment |
|-------------|---------------|---------------|-------|-----------------|
| | | | No. | Date |
| 100152 | GEL | Female 78 | 2 | 04OCT2018 Yes |
| . | . | . | 3 | 05OCT2018 Yes |
| . | . | . | 4 | 12OCT2018 Yes |
| <hr/> | | | | |
| 100153 | DROP | Female 81 | 2 | 17OCT2018 Yes |
| . | . | . | 3 | 18OCT2018 Yes |
| . | . | . | 4 | 24OCT2018 Yes |
| <hr/> | | | | |
| 100154 | GEL | Female 68 | 2 | 18OCT2018 Yes |
| . | . | . | 3 | 19OCT2018 Yes |
| . | . | . | 4 | 26OCT2018 Yes |
| <hr/> | | | | |
| 100155 | DROP | Female 79 | 2 | 18OCT2018 Yes |
| . | . | . | 3 | 19OCT2018 Yes |
| . | . | . | 4 | 26OCT2018 Yes |
| <hr/> | | | | |
| 100156 | GEL | Female 69 | 2 | 18OCT2018 Yes |
| . | . | . | 3 | 19OCT2018 Yes |
| . | . | . | 4 | 26OCT2018 Yes |
| <hr/> | | | | |
| 100201 | GEL | Female 80 | 2 | 07DEC2017 Yes |
| . | . | . | 3 | 09DEC2017 Yes |
| . | . | . | 4 | 13DEC2017 Yes |
| <hr/> | | | | |
| 100202 | DROP | Female 70 | 2 | 07DEC2017 Yes |
| . | . | . | 3 | 09DEC2017 Yes |
| . | . | . | 4 | 14DEC2017 Yes |
| <hr/> | | | | |
| 100203 | DROP | Female 76 | 2 | 14DEC2017 Yes |
| . | . | . | 3 | 15DEC2017 Yes |
| . | . | . | 4 | 20DEC2017 Yes |
| <hr/> | | | | |
| 100204 | GEL | Male 71 | 2 | 14DEC2017 Yes |
| . | . | . | 3 | 15DEC2017 Yes |
| . | . | . | 4 | 20DEC2017 Yes |
| <hr/> | | | | |
| 100205 | GEL | Male 75 | 2 | 08FEB2018 Yes |
| . | . | . | 3 | 09FEB2018 Yes |
| . | . | . | 4 | 14FEB2018 Yes |

Listing 11 (7 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit | Study Treatment |
|-------------|---------------|---------------|-------|-----------------|
| | | | No. | Date |
| 100206 | DROP | Female 81 | 2 | 11JAN2018 Yes |
| . | . | . | 3 | 12JAN2018 Yes |
| . | . | . | 4 | 18JAN2018 Yes |
| 100207 | DROP | Female 65 | 2 | 11JAN2018 Yes |
| . | . | . | 3 | 12JAN2018 Yes |
| . | . | . | 4 | 18JAN2018 Yes |
| 100208 | GEL | Female 79 | 2 | 11JAN2018 Yes |
| . | . | . | 3 | 12JAN2018 Yes |
| . | . | . | 4 | 18JAN2018 Yes |
| 100209 | GEL | Female 77 | 2 | 18JAN2018 Yes |
| 100210 | DROP | Female 70 | 2 | 18JAN2018 Yes |
| . | . | . | 3 | 19JAN2018 Yes |
| . | . | . | 4 | 24JAN2018 Yes |
| 100211 | GEL | Male 67 | 2 | 18JAN2018 Yes |
| . | . | . | 3 | 19JAN2018 Yes |
| . | . | . | 4 | 24JAN2018 Yes |
| 100212 | DROP | Female 82 | 2 | 18JAN2018 Yes |
| . | . | . | 3 | 19JAN2018 Yes |
| . | . | . | 4 | 24JAN2018 Yes |
| 100213 | DROP | Female 81 | 2 | 01FEB2018 Yes |
| . | . | . | 3 | 02FEB2018 Yes |
| . | . | . | 4 | 07FEB2018 Yes |
| 100214 | DROP | Female 77 | 2 | 08FEB2018 Yes |
| . | . | . | 3 | 09FEB2018 Yes |
| . | . | . | 4 | 14FEB2018 Yes |
| 100215 | GEL | Female 83 | 2 | 08FEB2018 Yes |
| . | . | . | 3 | 09FEB2018 Yes |
| . | . | . | 4 | 14FEB2018 Yes |
| 100216 | GEL | Female 74 | 2 | 15FEB2018 Yes |
| . | . | . | 3 | 16FEB2018 Yes |
| . | . | . | 4 | 21FEB2018 Yes |

Listing 11 (8 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit | Study Treatment |
|-------------|---------------|---------------|-------|-----------------|
| | | | No. | Date |
| 100217 | DROP | Female 72 | 2 | 08MAR2018 Yes |
| . | . | . | 3 | 09MAR2018 Yes |
| . | . | . | 4 | 14MAR2018 Yes |
| 100218 | DROP | Male 72 | 2 | 08MAR2018 Yes |
| . | . | . | 3 | 09MAR2018 Yes |
| . | . | . | 4 | 14MAR2018 Yes |
| 100219 | GEL | Female 83 | 2 | 15MAR2018 Yes |
| . | . | . | 3 | 16MAR2018 Yes |
| . | . | . | 4 | 21MAR2018 Yes |
| 100220 | GEL | Male 64 | 2 | 15MAR2018 Yes |
| . | . | . | 3 | 16MAR2018 Yes |
| . | . | . | 4 | 21MAR2018 Yes |
| 100221 | GEL | Female 76 | 2 | 05APR2018 Yes |
| . | . | . | 3 | 06APR2018 Yes |
| . | . | . | 4 | 11APR2018 Yes |
| 100222 | DROP | Female 76 | 2 | 12APR2018 Yes |
| . | . | . | 3 | 13APR2018 Yes |
| . | . | . | 4 | 18APR2018 Yes |
| 100223 | DROP | Male 61 | 2 | 12APR2018 Yes |
| . | . | . | 3 | 13APR2018 Yes |
| . | . | . | 4 | 18APR2018 Yes |
| 100224 | GEL | Female 75 | 2 | 26APR2018 Yes |
| . | . | . | 3 | 27APR2018 Yes |
| . | . | . | 4 | 02MAY2018 Yes |
| 100225 | DROP | Female 79 | 2 | 26APR2018 Yes |
| . | . | . | 3 | 27APR2018 Yes |
| . | . | . | 4 | 02MAY2018 Yes |
| 100226 | GEL | Female 74 | 2 | 26APR2018 Yes |
| . | . | . | 3 | 27APR2018 Yes |
| . | . | . | 4 | 02MAY2018 Yes |

Listing 11 (9 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit | Study Treatment | |
|-------------|---------------|---------------|-------|-----------------|-------------------------------|
| | | | No. | Date | administered after surgery |
| 100227 | DROP | Female 68 | 2 | 03MAY2018 Yes | |
| | | | . | 3 | 04MAY2018 Yes |
| | | | . | 4 | 09MAY2018 Yes |
| 100228 | GEL | Female 68 | 2 | 03MAY2018 Yes | |
| | | | . | 3 | 04MAY2018 Yes |
| | | | . | 4 | 09MAY2018 No |
| 100229 | GEL | Female 70 | 2 | 10MAY2018 Yes | |
| | | | . | 3 | 11MAY2018 Yes |
| | | | . | 4 | 16MAY2018 Yes |
| 100230 | GEL | Female 63 | 2 | 10MAY2018 Yes | |
| | | | . | 3 | 11MAY2018 Yes |
| | | | . | 4 | 16MAY2018 Yes |
| 100231 | DROP | Female 74 | 2 | 10MAY2018 Yes | |
| | | | . | 3 | 11MAY2018 Yes |
| | | | . | 4 | 16MAY2018 Yes |
| 100232 | DROP | Female 73 | 2 | 10MAY2018 Yes | |
| | | | . | 3 | 11MAY2018 Yes |
| | | | . | 4 | 16MAY2018 Yes |
| 100233 | GEL | Female 72 | 2 | 24MAY2018 Yes | |
| | | | . | 3 | 25MAY2018 Yes |
| | | | . | 4 | 30MAY2018 Yes |
| 100234 | GEL | Female 73 | 2 | 24MAY2018 Yes | |
| | | | . | 3 | 25MAY2018 Yes |
| | | | . | 4 | 30MAY2018 Yes |
| 100235 | DROP | Male 64 | 2 | 31MAY2018 Yes | |
| | | | . | 3 | 01JUN2018 Yes |
| | | | . | 4 | 06JUN2018 Yes |
| 100236 | DROP | Female 70 | 2 | 31MAY2018 Yes | |
| | | | . | 3 | 01JUN2018 Yes |
| | | | . | 4 | 06JUN2018 Yes |

Listing 11 (10 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Study Treatment | |
|-------------|---------------|---------------|--------------|-----------------|-------------------------------|
| | | | | Date | administered after surgery |
| 100237 | DROP | Male 73 | 2 | 07JUN2018 | Yes |
| . | . | . | 3 | 08JUN2018 | Yes |
| . | . | . | 4 | 13JUN2018 | Yes |
| 100238 | GEL | Male 78 | 2 | 07JUN2018 | Yes |
| . | . | . | 3 | 08JUN2018 | Yes |
| . | . | . | 4 | 13JUN2018 | Yes |
| 100239 | DROP | Female 80 | 2 | 14JUN2018 | Yes |
| . | . | . | 3 | 15JUN2018 | Yes |
| . | . | . | 4 | 20JUN2018 | Yes |
| 100241 | GEL | Female 74 | 2 | 25OCT2018 | Yes |
| . | . | . | 3 | 26OCT2018 | Yes |
| . | . | . | 4 | 31OCT2018 | Yes |
| 100242 | GEL | Female 67 | 2 | 08NOV2018 | Yes |
| . | . | . | 3 | 09NOV2018 | Yes |
| . | . | . | 4 | 14NOV2018 | Yes |
| 100243 | DROP | Male 74 | 2 | 06DEC2018 | Yes |
| . | . | . | 3 | 07DEC2018 | Yes |
| . | . | . | 4 | 12DEC2018 | Yes |
| 100244 | GEL | Female 66 | 2 | 13DEC2018 | Yes |
| . | . | . | 3 | 14DEC2018 | Yes |
| . | . | . | 4 | 19DEC2018 | Yes |
| 100245 | DROP | Female 69 | 2 | 13DEC2018 | Yes |
| . | . | . | 3 | 14DEC2018 | Yes |
| . | . | . | 4 | 19DEC2018 | Yes |
| 100301 | GEL | Female 68 | 2 | 19OCT2017 | Yes |
| . | . | . | 3 | 20OCT2017 | Yes |
| . | . | . | 4 | 25OCT2017 | Yes |
| 100302 | GEL | Male 61 | 2 | 02NOV2017 | Yes |
| . | . | . | 3 | 03NOV2017 | Yes |
| . | . | . | 4 | 09NOV2017 | Yes |

Listing 11 (11 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Study Treatment | |
|-------------|---------------|---------------|--------------|-----------------|-------------------------------|
| | | | | Date | administered after surgery |
| 100303 | DROP | Female 73 | 2 | 02NOV2017 | Yes |
| . | . | . | 3 | 03NOV2017 | Yes |
| . | . | . | 4 | 09NOV2017 | Yes |
| 100304 | DROP | Male 58 | 2 | 16NOV2017 | Yes |
| . | . | . | 3 | 17NOV2017 | Yes |
| . | . | . | 4 | 23NOV2017 | Yes |
| 100305 | DROP | Female 85 | 2 | 16NOV2017 | Yes |
| . | . | . | 3 | 17NOV2017 | Yes |
| . | . | . | 4 | 23NOV2017 | Yes |
| 100306 | DROP | Female 84 | 2 | 22NOV2017 | No |
| 100307 | GEL | Female 73 | 2 | 29NOV2017 | Yes |
| . | . | . | 3 | 30NOV2017 | Yes |
| . | . | . | 4 | 06DEC2017 | Yes |
| 100308 | GEL | Female 85 | 2 | 29NOV2017 | No |
| 100309 | DROP | Female 61 | 2 | 29NOV2017 | Yes |
| . | . | . | 3 | 30NOV2017 | Yes |
| . | . | . | 4 | 06DEC2017 | Yes |
| 100310 | GEL | Female 73 | 2 | 30NOV2017 | Yes |
| . | . | . | 3 | 01DEC2017 | Yes |
| . | . | . | 4 | 06DEC2017 | Yes |
| 100311 | GEL | Female 83 | 2 | 05DEC2017 | Yes |
| . | . | . | 3 | 06DEC2017 | Yes |
| . | . | . | 4 | 13DEC2017 | Yes |
| 100312 | DROP | Female 71 | 2 | 05DEC2017 | Yes |
| . | . | . | 3 | 06DEC2017 | Yes |
| . | . | . | 4 | 13DEC2017 | Yes |
| 100313 | GEL | Male 71 | 2 | 04DEC2017 | No |
| 100314 | DROP | Male 67 | 2 | 05DEC2017 | Yes |
| . | . | . | 3 | 06DEC2017 | Yes |
| . | . | . | 4 | 13DEC2017 | Yes |

Listing 11 (12 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit | Study Treatment |
|-------------|---------------|---------------|-------|-----------------|
| | | | No. | Date |
| 100315 | GEL | Female 65 | 2 | 05DEC2017 Yes |
| . | . | . | 3 | 06DEC2017 Yes |
| . | . | . | 4 | 13DEC2017 Yes |
| 100316 | DROP | Male 76 | 2 | 05DEC2017 Yes |
| . | . | . | 3 | 06DEC2017 Yes |
| . | . | . | 4 | 13DEC2017 Yes |
| 100317 | GEL | Male 85 | 2 | 05DEC2017 Yes |
| . | . | . | 3 | 06DEC2017 Yes |
| . | . | . | 4 | 14DEC2017 Yes |
| 100318 | GEL | Female 80 | 2 | 05DEC2017 Yes |
| . | . | . | 3 | 06DEC2017 Yes |
| . | . | . | 4 | 13DEC2017 Yes |
| 100319 | DROP | Male 70 | 2 | 05DEC2017 Yes |
| . | . | . | 3 | 06DEC2017 Yes |
| . | . | . | 4 | 13DEC2017 Yes |
| 100320 | DROP | Male 69 | 2 | 05DEC2017 Yes |
| . | . | . | 3 | 06DEC2017 Yes |
| . | . | . | 4 | 13DEC2017 Yes |
| 100321 | GEL | Male 72 | 2 | 11DEC2017 Yes |
| . | . | . | 3 | 12DEC2017 Yes |
| . | . | . | 4 | 27DEC2017 Yes |
| 100322 | GEL | Male 80 | 2 | 13DEC2017 Yes |
| . | . | . | 3 | 14DEC2017 Yes |
| . | . | . | 4 | 19DEC2017 Yes |
| 100323 | DROP | Female 76 | 2 | 13DEC2017 Yes |
| . | . | . | 3 | 14DEC2017 Yes |
| . | . | . | 4 | 19DEC2017 Yes |
| 100324 | DROP | Male 65 | 2 | 18DEC2017 Yes |
| . | . | . | 3 | 19DEC2017 Yes |
| . | . | . | 4 | 27DEC2017 Yes |
| 100325 | GEL | Female 83 | 2 | 18DEC2017 Yes |

Listing 11 (13 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Study Treatment | |
|-------------|---------------|---------------|--------------|-----------------|-------------------------------|
| | | | | Date | administered after surgery |
| 100326 | DROP | Male 81 | 2 | 18DEC2017 | Yes |
| . | . | . | 3 | 19DEC2017 | No |
| . | . | . | 4 | 27DEC2017 | Yes |
| ----- | | | | | |
| 100327 | GEL | Female 73 | 2 | 18DEC2017 | Yes |
| . | . | . | 3 | 19DEC2017 | Yes |
| . | . | . | 4 | 27DEC2017 | Yes |
| ----- | | | | | |
| 100328 | DROP | Male 82 | 2 | 18DEC2017 | Yes |
| . | . | . | 3 | 19DEC2017 | Yes |
| . | . | . | 4 | 27DEC2017 | Yes |
| ----- | | | | | |
| 100329 | GEL | Male 74 | 2 | 18DEC2017 | Yes |
| . | . | . | 3 | 19DEC2017 | Yes |
| . | . | . | 4 | 27DEC2017 | Yes |
| ----- | | | | | |
| 100330 | DROP | Male 61 | 2 | 19DEC2017 | Yes |
| . | . | . | 3 | 20DEC2017 | Yes |
| . | . | . | 4 | 27DEC2017 | Yes |
| ----- | | | | | |
| 100331 | GEL | Female 71 | 2 | 19DEC2017 | Yes |
| . | . | . | 3 | 20DEC2017 | Yes |
| . | . | . | 4 | 27DEC2017 | Yes |
| ----- | | | | | |
| 100332 | DROP | Male 82 | 2 | 12JAN2018 | Yes |
| . | . | . | 3 | 13JAN2018 | Yes |
| . | . | . | 4 | 19JAN2018 | Yes |
| ----- | | | | | |
| 100333 | DROP | Male 62 | 2 | 25JAN2018 | Yes |
| . | . | . | 3 | 26JAN2018 | Yes |
| . | . | . | 4 | 01FEB2018 | Yes |
| ----- | | | | | |
| 100334 | GEL | Male 72 | 2 | 24JAN2018 | Yes |
| . | . | . | 3 | 25JAN2018 | Yes |
| . | . | . | 4 | 01FEB2018 | Yes |
| ----- | | | | | |
| 100335 | DROP | Female 80 | 2 | 06FEB2018 | Yes |
| . | . | . | 3 | 07FEB2018 | Yes |
| . | . | . | 4 | 12FEB2018 | Yes |

Listing 11 (14 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Study Treatment | |
|-------------|---------------|---------------|--------------|-----------------|-------------------------------|
| | | | | Date | administered after surgery |
| 100336 | GEL | Female 82 | 2 | 06MAR2018 | Yes |
| . | . | . | 3 | 07MAR2018 | Yes |
| . | . | . | 4 | 12MAR2018 | Yes |
| 100337 | GEL | Male 72 | 2 | 16MAR2018 | No |
| 100338 | DROP | Female 87 | 2 | 21MAR2018 | Yes |
| . | . | . | 3 | 22MAR2018 | Yes |
| . | . | . | 4 | 27MAR2018 | Yes |
| 100339 | GEL | Male 56 | 2 | 28MAR2018 | Yes |
| . | . | . | 3 | 29MAR2018 | Yes |
| . | . | . | 4 | 05APR2018 | Yes |
| 100340 | DROP | Male 83 | 2 | 12APR2018 | Yes |
| . | . | . | 3 | 13APR2018 | Yes |
| . | . | . | 4 | 19APR2018 | Yes |
| 100341 | GEL | Male 88 | 2 | 12APR2018 | Yes |
| . | . | . | 3 | 13APR2018 | Yes |
| . | . | . | 4 | 19APR2018 | Yes |
| 100342 | DROP | Female 86 | 2 | 12APR2018 | Yes |
| . | . | . | 3 | 13APR2018 | Yes |
| . | . | . | 4 | 19APR2018 | Yes |
| 100343 | GEL | Male 74 | 2 | 10APR2018 | Yes |
| . | . | . | 3 | 11APR2018 | Yes |
| . | . | . | 4 | 17APR2018 | Yes |
| 100344 | DROP | Female 68 | 2 | 10APR2018 | Yes |
| . | . | . | 3 | 11APR2018 | Yes |
| . | . | . | 4 | 17APR2018 | Yes |
| 100345 | GEL | Male 48 | 2 | 10APR2018 | Yes |
| . | . | . | 3 | 11APR2018 | Yes |
| . | . | . | 4 | 17APR2018 | Yes |
| 100346 | DROP | Female 77 | 2 | 12APR2018 | Yes |
| . | . | . | 3 | 13APR2018 | Yes |
| . | . | . | 4 | 19APR2018 | Yes |

Listing 11 (15 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Study Treatment | |
|-------------|---------------|---------------|--------------|-----------------|-------------------------------|
| | | | | Date | administered after surgery |
| 100347 | GEL | Male 58 | 2 | 18APR2018 | Yes |
| . | . | . | 3 | 19APR2018 | Yes |
| . | . | . | 4 | 24APR2018 | Yes |
| 100348 | GEL | Female 38 | 2 | 24APR2018 | Yes |
| . | . | . | 3 | 25APR2018 | Yes |
| . | . | . | 4 | 30APR2018 | Yes |
| 100349 | DROP | Male 71 | 2 | 24MAY2018 | Yes |
| . | . | . | 3 | 25MAY2018 | Yes |
| . | . | . | 4 | 30MAY2018 | Yes |
| 100350 | DROP | Female 67 | 2 | 22MAY2018 | Yes |
| . | . | . | 3 | 23MAY2018 | Yes |
| . | . | . | 4 | 30MAY2018 | Yes |
| 100351 | GEL | Female 79 | 2 | 25MAY2018 | Yes |
| . | . | . | 3 | 26MAY2018 | Yes |
| . | . | . | 4 | 01JUN2018 | Yes |
| 100352 | DROP | Female 63 | 2 | 29MAY2018 | Yes |
| . | . | . | 3 | 30MAY2018 | Yes |
| . | . | . | 4 | 06JUN2018 | Yes |
| 100353 | GEL | Female 72 | 2 | 07JUN2018 | Yes |
| . | . | . | 3 | 08JUN2018 | Yes |
| . | . | . | 4 | 14JUN2018 | Yes |
| 100354 | GEL | Female 80 | 2 | 07JUN2018 | Yes |
| . | . | . | 3 | 08JUN2018 | Yes |
| . | . | . | 4 | 14JUN2018 | Yes |
| 100355 | DROP | Female 80 | 2 | 13JUN2018 | Yes |
| . | . | . | 3 | 14JUN2018 | Yes |
| . | . | . | 4 | 21JUN2018 | Yes |
| 100356 | GEL | Male 74 | 2 | 18JUN2018 | Yes |
| . | . | . | 3 | 19JUN2018 | Yes |
| . | . | . | 4 | 26JUN2018 | Yes |

Listing 11 (16 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Visit | Study Treatment |
|-------------|---------------|---------------|--------------|-----------|-------------------------------|
| | | | | Date | administered after surgery |
| 200101 | GEL | Female 66 | 2 | 16JAN2018 | Yes |
| . | . | . | 3 | 17JAN2018 | Yes |
| . | . | . | 4 | 24JAN2018 | Yes |
| 200102 | DROP | Female 76 | 2 | 30JAN2018 | Yes |
| . | . | . | 3 | 31JAN2018 | Yes |
| . | . | . | 4 | 05FEB2018 | Yes |
| 200103 | DROP | Male 82 | 2 | 13FEB2018 | Yes |
| . | . | . | 3 | 14FEB2018 | Yes |
| . | . | . | 4 | 19FEB2018 | Yes |
| 200104 | GEL | Female 78 | 2 | 08MAY2018 | Yes |
| . | . | . | 3 | 09MAY2018 | Yes |
| . | . | . | 4 | 16MAY2018 | No |
| 200105 | GEL | Female 65 | 2 | 29MAY2018 | Yes |
| . | . | . | 3 | 30MAY2018 | Yes |
| . | . | . | 4 | 06JUN2018 | Yes |
| 200106 | DROP | Female 75 | 2 | 26JUN2018 | Yes |
| . | . | . | 3 | 27JUN2018 | Yes |
| . | . | . | 4 | 04JUL2018 | Yes |
| 200107 | DROP | Female 54 | 2 | 03JUL2018 | Yes |
| . | . | . | 3 | 04JUL2018 | No |
| 200108 | GEL | Male 77 | 2 | 04SEP2018 | Yes |
| . | . | . | 3 | 05SEP2018 | Yes |
| . | . | . | 4 | 12SEP2018 | Yes |
| 200109 | GEL | Female 84 | 2 | 02OCT2018 | Yes |
| . | . | . | 3 | 03OCT2018 | Yes |
| . | . | . | 4 | 10OCT2018 | No |
| 200110 | DROP | Male 64 | 2 | 09OCT2018 | Yes |
| . | . | . | 3 | 10OCT2018 | Yes |
| . | . | . | 4 | 17OCT2018 | Yes |
| 200111 | GEL | Male 73 | 2 | 06NOV2018 | Yes |
| . | . | . | 3 | 07NOV2018 | Yes |
| . | . | . | 4 | 14NOV2018 | Yes |

Listing 11 (17 of 17): Study treatment administration during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Study Treatment administered after surgery | |
|-------------|---------------|---------------|--------------|--|-----|
| | | | | Date | |
| 200112 | DROP | Male 85 | 2 | 13NOV2018 | Yes |
| . | . | . | 3 | 14NOV2018 | Yes |
| . | . | . | 4 | 21NOV2018 | Yes |
| 200113 | DROP | Male 77 | 2 | 13NOV2018 | Yes |
| . | . | . | 3 | 14NOV2018 | Yes |
| . | . | . | 4 | 21NOV2018 | Yes |
| 200114 | DROP | Female 64 | 2 | 27NOV2018 | No |
| 200115 | GEL | Female 70 | 2 | 18DEC2018 | Yes |
| . | . | . | 3 | 19DEC2018 | Yes |
| . | . | . | 4 | 27DEC2018 | Yes |
| 200202 | DROP | Female 71 | 2 | 18JUN2018 | Yes |
| . | . | . | 3 | 19JUN2018 | Yes |
| . | . | . | 4 | 25JUN2018 | Yes |
| 200203 | GEL | Male 66 | 2 | 26JUN2018 | Yes |
| . | . | . | 3 | 27JUN2018 | Yes |
| . | . | . | 4 | 02JUL2018 | Yes |
| 200204 | GEL | Male 58 | 2 | 03JUL2018 | Yes |
| . | . | . | 3 | 04JUL2018 | Yes |
| . | . | . | 4 | 10JUL2018 | Yes |

SAS program: L03_List_11.sas - SAS dataset name(s): RAND,DEMOGRAPHY,TREATMENT

Listing 12 (1 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (2 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (3 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (5 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (6 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (8 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (9 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (10 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (12 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (13 of 21): Signs/Symptoms of ocular inflammation during the study

| Sbj | Study | Age | Visit | Anterior chamber flare | Anterior chamber cells | Conjunctival hyperemia | Lid edema | Corneal edema | Ocular discomfort | Ocular pain | Ocular photophobia | Ocular tearing |
|--------|-------|--------|--------|------------------------|------------------------|------------------------|-----------|---------------|-------------------|-------------|--------------------|----------------|
| Code | drug | Sex | (year) | No. | Date | | | | | | | |
| 100301 | GEL | Female | 68 | 3 | 20OCT2017 | None | None | None | None | None | None | None |
| . | . | . | 4 | 25OCT2017 | None | None | None | None | None | None | None | None |
| . | . | . | 5 | 03NOV2017 | None | None | None | None | None | None | None | None |
| . | . | . | 6 | 20DEC2017 | None | None | None | None | None | Mild | None | None |
| . | . | . | 7 | 13DEC2017 | . | . | . | . | . | . | . | . |
| 100302 | GEL | Male | 61 | 3 | 03NOV2017 | None | None | Mild | None | None | Mild | Mild |
| . | . | . | 4 | 09NOV2017 | None | None | Mild | None | None | Mild | None | None |
| . | . | . | 5 | 17NOV2017 | None | None | Mild | None | None | Mild | None | None |
| . | . | . | 6 | 05JAN2018 | None | None | None | None | None | None | Mild | Mild |
| . | . | . | 7 | 29NOV2017 | . | . | . | . | . | . | . | . |
| 100303 | DROP | Female | 73 | 3 | 03NOV2017 | None | None | None | None | None | None | None |
| . | . | . | 4 | 09NOV2017 | None | None | None | None | None | None | None | None |
| . | . | . | 5 | 17NOV2017 | None | None | None | None | None | None | None | None |
| . | . | . | 6 | 05JAN2018 | None | None | None | None | None | Mild | None | None |
| 100304 | DROP | Male | 58 | 3 | 17NOV2017 | None | None | None | None | None | None | None |
| . | . | . | 4 | 23NOV2017 | None | None | None | None | None | None | None | None |
| . | . | . | 5 | 30NOV2017 | None | None | None | None | None | None | Mild | Mild |
| . | . | . | 6 | 16JAN2018 | None | None | None | None | None | None | None | None |
| 100305 | DROP | Female | 85 | 3 | 17NOV2017 | None | None | None | None | None | None | None |
| . | . | . | 4 | 23NOV2017 | None | None | None | None | None | None | None | None |
| . | . | . | 5 | 30NOV2017 | None | None | None | None | None | None | None | None |
| . | . | . | 6 | 16JAN2018 | None | None | None | None | None | None | Mild | Mild |
| 100307 | GEL | Female | 73 | 3 | 30NOV2017 | None | None | None | None | None | Mild | Mild |
| . | . | . | 4 | 06DEC2017 | None | None | None | None | None | None | Mild | Mild |
| . | . | . | 5 | 14DEC2017 | None | None | None | None | None | None | None | None |
| . | . | . | 6 | 29JAN2018 | None | None | None | None | None | None | None | None |
| 100309 | DROP | Female | 61 | 3 | 30NOV2017 | None | None | None | None | None | None | None |
| . | . | . | 4 | 06DEC2017 | None | None | None | None | None | None | None | None |
| . | . | . | 5 | 14DEC2017 | None | None | None | None | None | None | None | None |
| . | . | . | 6 | 29JAN2018 | None | None | None | None | None | None | None | None |
| 100310 | GEL | Female | 73 | 3 | 01DEC2017 | None | None | Mild | None | None | Mild | Mild |
| . | . | . | 4 | 06DEC2017 | None | None | None | None | None | None | Mild | Mild |
| . | . | . | 5 | 14DEC2017 | None | None | None | None | None | None | Mild | Mild |
| . | . | . | 6 | 29JAN2018 | None | None | None | None | None | Mild | Mild | Mild |

Listing 12 (14 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (15 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (16 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (18 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (19 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (20 of 21): Signs/Symptoms of ocular inflammation during the study

Listing 12 (21 of 21): Signs/Symptoms of ocular inflammation during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Anterior chamber flare | | | Anterior chamber cells | | | Conjunctival hyperemia | | | Lid edema | | | Ocular edema | Ocular pain | Ocular discomfort | Ocular photophobia | Ocular tearing |
|-------------|---------------|-------------------|--------------|------------------------|-------|-----------|------------------------|-------|-------|------------------------|------|------------|-------------|---------|------|--------------|-------------|-------------------|--------------------|----------------|
| | | | | chamber flare | cells | hyperemia | lid edema | edema | edema | discomfort | pain | discomfort | photophobia | tearing | | | | | | |
| 200202 | DROP | Female 71 | 3 | 19JUN2018 | None | None | None | None | None | None | None | None | None | None | None | None | None | None | | |
| . | . | . | 4 | 25JUN2018 | None | None | None | None | None | None | None | None | None | None | None | None | None | None | | |
| . | . | . | 5 | 03JUL2018 | None | None | None | None | None | None | None | None | None | None | None | None | None | None | | |
| . | . | . | 6 | 17AUG2018 | None | None | None | None | None | None | None | None | None | None | None | None | None | None | | |
| . | . | . | 7 | 06JUL2018 | . | . | . | . | . | . | . | . | . | . | . | . | . | . | | |
| 200203 | GEL | Male 66 | 3 | 27JUN2018 | None | Mild | Mild | None | None | None | None | None | None | None | None | None | None | None | | |
| . | . | . | 4 | 02JUL2018 | None | None | Mild | None | None | None | None | None | None | None | None | None | None | None | | |
| . | . | . | 5 | 12JUL2018 | None | None | None | None | None | None | None | None | None | Mild | None | None | None | None | | |
| . | . | . | 6 | 04SEP2018 | None | None | None | None | None | None | None | None | None | None | None | None | None | None | | |
| 200204 | GEL | Male 58 | 3 | 04JUL2018 | None | Mild | Mild | None | None | None | None | None | None | None | None | None | None | None | | |
| . | . | . | 4 | 10JUL2018 | None | None | None | None | None | None | None | None | None | Mild | None | None | None | None | | |
| . | . | . | 5 | 18JUL2018 | None | None | None | None | None | None | None | None | None | None | None | None | None | None | | |
| . | . | . | 6 | 04SEP2018 | None | None | None | None | None | None | None | None | None | None | None | None | None | None | | |

SAS program: L03_List_12.sas - SAS dataset name(s): RAND, DEMOGRAPHY, OCULAR_INFLA

Listing 13 (1 of #): Microbial load during the study

NO data in the database !!! (dataset ANTIBIOGRAM)

| Sbj Code | Study drug | Age (year) | Visit No. | Date | Microbial species found | Antibiotic tested | |
|-------------|---------------|---------------|--------------|----------|-------------------------|-------------------|--------------------|
| | | | | | | Name | Antibiogram result |
| ##-## | #### | ##### | ### | 3 | ##/##/## | ##### | ##### |
| | | | | | | Netilmicin | ##### |
| | | | | | | Cephuroxime | ##### |
| | | | | | | Other 1: ##### | ##### |
| | | | | | | Other 2: ##### | ##### |
| | | | | | | Other 3: ##### | ##### |
| | | | | | ##### | Netilmicin | ##### |
| | | | | | | Cephuroxime | ##### |
| | | | | | | Other 1: ##### | ##### |
| | | | | | | Other 2: ##### | ##### |
| | | | | | | Other 3: ##### | ##### |
| | | | | | ##### | Netilmicin | ##### |
| | | | | | | Cephuroxime | ##### |
| | | | | | | Other 1: ##### | ##### |
| | | | | | | Other 2: ##### | ##### |
| | | | | | | Other 3: ##### | ##### |
| | | | 4 | ##/##/## | ##### | Netilmicin | ##### |
| | | | | | | Cephuroxime | ##### |
| | | | | | | Other 1: ##### | ##### |
| | | | | | | Other 2: ##### | ##### |
| | | | | | | Other 3: ##### | ##### |
| | | | | | ##### | Netilmicin | ##### |
| | | | | | | Cephuroxime | ##### |
| | | | | | | Other 1: ##### | ##### |
| | | | | | | Other 2: ##### | ##### |
| | | | | | | Other 3: ##### | ##### |
| | | | | | ##### | Netilmicin | ##### |
| | | | | | | Cephuroxime | ##### |
| | | | | | | Other 1: ##### | ##### |
| | | | | | | Other 2: ##### | ##### |
| | | | | | | Other 3: ##### | ##### |

SAS program: L03_List_13.sas - SAS dataset(s):

Listing 14 (1 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Global | | | | |
|-------------|---------------|-------------------|--------------|------------|---------|----------|----------------|-------------------------|
| | | | | Performed? | Burning | Stinging | Blurred vision | subjective tolerability |
| 100101 | DROP | Female 84 | 3 | 26OCT2017 | Yes | None | None | None |
| . | . | . | 4 | 02NOV2017 | Yes | None | None | None |
| . | . | . | 5 | 08NOV2017 | Yes | None | None | None |
| 100102 | GEL | Male 80 | 3 | 01NOV2017 | Yes | None | None | None |
| . | . | . | 4 | 07NOV2017 | Yes | None | None | None |
| . | . | . | 5 | 15NOV2017 | Yes | None | None | None |
| 100104 | GEL | Male 70 | 3 | 08NOV2017 | Yes | None | None | None |
| . | . | . | 4 | 14NOV2017 | Yes | None | None | None |
| . | . | . | 5 | 22NOV2017 | Yes | None | None | None |
| 100105 | DROP | Female 85 | 3 | 09NOV2017 | Yes | None | None | None |
| . | . | . | 4 | 15NOV2017 | Yes | None | None | None |
| . | . | . | 5 | 23NOV2017 | Yes | None | None | None |
| 100106 | GEL | Male 56 | 3 | 16NOV2017 | Yes | None | None | None |
| . | . | . | 4 | 22NOV2017 | Yes | None | None | None |
| . | . | . | 5 | 30NOV2017 | Yes | None | None | None |
| 100107 | DROP | Female 82 | 3 | 29NOV2017 | Yes | None | None | None |
| . | . | . | 4 | 05DEC2017 | Yes | None | None | None |
| . | . | . | 5 | 13DEC2017 | Yes | None | None | None |
| 100108 | DROP | Female 73 | 3 | 07DEC2017 | Yes | None | None | None |
| . | . | . | 4 | 13DEC2017 | Yes | None | None | None |
| . | . | . | 5 | 21DEC2017 | Yes | None | None | None |
| 100109 | GEL | Female 56 | 3 | 13DEC2017 | Yes | None | None | None |
| . | . | . | 4 | 19DEC2017 | Yes | None | None | None |
| . | . | . | 5 | 27DEC2017 | Yes | None | None | None |
| 100110 | DROP | Female 75 | 3 | 14DEC2017 | Yes | None | None | None |
| . | . | . | 4 | 20DEC2017 | Yes | None | None | None |
| . | . | . | 5 | 28DEC2017 | Yes | None | None | None |
| 100111 | DROP | Female 60 | 3 | 14DEC2017 | Yes | None | None | None |
| . | . | . | 4 | 20DEC2017 | Yes | None | None | None |
| . | . | . | 5 | 28DEC2017 | Yes | None | None | None |

Listing 14 (2 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Date | Perfomed? | | | Blurred vision | Global subjective tolerability |
|-------------|---------------|-------------------|--------------|-------------|-----------|----------|------|-------------------|--------------------------------------|
| | | | | | Burning | Stinging | | | |
| 100112 | GEL | Male | 73 | 3 04JAN2018 | Yes | None | None | None | None |
| | | | 4 | 10JAN2018 | Yes | None | None | None | None |
| | | | 5 | 17JAN2018 | Yes | None | None | None | None |
| 100113 | GEL | Female | 77 | 3 04JAN2018 | Yes | None | None | None | None |
| | | | 4 | 10JAN2018 | Yes | None | None | None | None |
| | | | 5 | 17JAN2018 | Yes | None | None | None | None |
| 100114 | GEL | Male | 64 | 3 04JAN2018 | Yes | None | None | None | None |
| | | | 4 | 10JAN2018 | Yes | None | None | None | None |
| | | | 5 | 17JAN2018 | Yes | None | None | None | None |
| 100115 | DROP | Male | 76 | 3 05JAN2018 | Yes | None | None | None | None |
| | | | 4 | 11JAN2018 | Yes | None | None | None | None |
| | | | 5 | 18JAN2018 | Yes | None | None | None | None |
| 100116 | GEL | Male | 62 | 3 05JAN2018 | Yes | None | None | None | None |
| | | | 4 | 11JAN2018 | Yes | None | None | None | None |
| | | | 5 | 19JAN2018 | Yes | None | None | None | None |
| 100117 | DROP | Female | 51 | 3 11JAN2018 | Yes | None | None | None | None |
| | | | 4 | 17JAN2018 | Yes | None | None | None | None |
| | | | 5 | 23JAN2018 | Yes | None | None | None | None |
| 100118 | DROP | Female | 78 | 3 18JAN2018 | Yes | None | None | None | None |
| | | | 4 | 24JAN2018 | Yes | None | None | None | None |
| | | | 5 | 31JAN2018 | Yes | None | None | None | None |
| 100119 | DROP | Female | 72 | 3 25JAN2018 | Yes | None | None | None | None |
| | | | 4 | 31JAN2018 | Yes | None | None | None | None |
| | | | 5 | 08FEB2018 | Yes | None | None | None | None |
| 100120 | GEL | Male | 79 | 3 25JAN2018 | Yes | None | None | None | None |
| | | | 4 | 31JAN2018 | Yes | None | None | None | None |
| | | | 5 | 07FEB2018 | Yes | None | None | None | None |
| 100121 | GEL | Male | 80 | 3 25JAN2018 | Yes | None | None | None | None |
| | | | 4 | 31JAN2018 | Yes | None | None | None | None |
| | | | 5 | 07FEB2018 | Yes | None | None | None | None |

Listing 14 (3 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Perfomed? | | | Blurred vision | Global subjective tolerability |
|-------------|---------------|-------------------|--------------|-----------|---------|----------|-------------------|--------------------------------------|
| | | | | Date | Burning | Stinging | | |
| 100122 | DROP | Female 76 | 3 | 26JAN2018 | Yes | None | None | None |
| | | | 4 | 01FEB2018 | Yes | None | None | None |
| | | | 5 | 08FEB2018 | Yes | None | None | None |
| 100123 | DROP | Female 76 | 3 | 26JAN2018 | Yes | None | None | None |
| | | | 4 | 01FEB2018 | Yes | None | None | None |
| | | | 5 | 08FEB2018 | Yes | None | None | None |
| 100124 | GEL | Female 71 | 3 | 02FEB2018 | Yes | None | None | None |
| | | | 4 | 08FEB2018 | Yes | None | None | None |
| | | | 5 | 16FEB2018 | Yes | None | None | None |
| 100125 | GEL | Female 62 | 3 | 02FEB2018 | Yes | None | None | None |
| | | | 4 | 08FEB2018 | Yes | None | None | None |
| | | | 5 | 16FEB2018 | Yes | None | None | None |
| 100126 | GEL | Female 85 | 3 | 08FEB2018 | Yes | None | None | None |
| | | | 4 | 14FEB2018 | Yes | None | None | None |
| | | | 5 | 21FEB2018 | Yes | None | None | None |
| 100127 | GEL | Female 68 | 3 | 09FEB2018 | Yes | None | None | None |
| | | | 4 | 15FEB2018 | Yes | None | None | None |
| | | | 5 | 24FEB2018 | Yes | None | None | None |
| 100128 | DROP | Male 80 | 3 | 09FEB2018 | Yes | None | None | None |
| | | | 4 | 15FEB2018 | Yes | None | None | None |
| | | | 5 | 24FEB2018 | Yes | None | None | None |
| 100129 | DROP | Female 78 | 3 | 09FEB2018 | Yes | None | None | None |
| | | | 4 | 15FEB2018 | Yes | None | None | None |
| | | | 5 | 23FEB2018 | Yes | None | None | None |
| 100130 | GEL | Male 66 | 3 | 22FEB2018 | Yes | None | None | None |
| | | | 4 | 28FEB2018 | Yes | None | None | None |
| | | | 5 | 07MAR2018 | Yes | None | None | None |
| 100131 | DROP | Female 77 | 3 | 22FEB2018 | Yes | None | None | None |
| | | | 4 | 28FEB2018 | Yes | None | None | None |
| | | | 5 | 07MAR2018 | Yes | None | None | None |

Listing 14 (4 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Date | Performed? | | | Blurred vision | Global subjective tolerability |
|-------------|---------------|-------------------|--------------|------|------------|----------|------|-------------------|--------------------------------------|
| | | | | | Burning | Stinging | | | |
| 100132 | DROP | Male | 69 | 3 | 08MAR2018 | Yes | None | None | None |
| | | | . | 4 | 14MAR2018 | Yes | None | None | None |
| | | | . | 5 | 21MAR2018 | Yes | None | None | None |
| 100133 | GEL | Male | 74 | 3 | 08MAR2018 | Yes | None | None | None |
| | | | . | 4 | 14MAR2018 | Yes | None | None | None |
| | | | . | 5 | 21MAR2018 | Yes | None | None | None |
| 100134 | DROP | Female | 66 | 3 | 08MAR2018 | Yes | None | None | None |
| | | | . | 4 | 14MAR2018 | Yes | None | None | None |
| | | | . | 5 | 21MAR2018 | Yes | None | None | None |
| 100135 | GEL | Male | 69 | 3 | 16MAR2018 | Yes | None | None | None |
| | | | . | 4 | 22MAR2018 | Yes | None | None | None |
| | | | . | 5 | 29MAR2018 | Yes | None | None | None |
| 100136 | GEL | Female | 90 | 3 | 06APR2018 | Yes | None | None | None |
| | | | . | 4 | 12APR2018 | Yes | None | None | None |
| | | | . | 5 | 20APR2018 | Yes | None | None | None |
| 100137 | DROP | Female | 62 | 3 | 20APR2018 | Yes | None | None | None |
| | | | . | 4 | 26APR2018 | Yes | None | None | None |
| | | | . | 5 | 04MAY2018 | Yes | None | None | None |
| 100138 | GEL | Male | 63 | 3 | 20APR2018 | Yes | None | None | None |
| | | | . | 4 | 26APR2018 | Yes | None | None | None |
| | | | . | 5 | 04MAY2018 | Yes | None | None | None |
| 100139 | DROP | Female | 71 | 3 | 27APR2018 | Yes | None | None | None |
| | | | . | 4 | 03MAY2018 | Yes | None | None | None |
| | | | . | 5 | 11MAY2018 | Yes | None | None | None |
| 100140 | GEL | Male | 81 | 3 | 03MAY2018 | Yes | None | None | None |
| | | | . | 4 | 09MAY2018 | Yes | None | None | None |
| | | | . | 5 | 17MAY2018 | Yes | None | None | None |
| 100141 | DROP | Female | 74 | 3 | 03MAY2018 | Yes | None | None | None |
| | | | . | 4 | 10MAY2018 | Yes | None | None | None |
| | | | . | 5 | 16MAY2018 | Yes | None | None | None |

Listing 14 (5 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Global | | | | |
|-------------|---------------|---------------|--------------|------------|---------|----------|----------------|-------------------------|
| | | | | Performed? | Burning | Stinging | Blurred vision | subjective tolerability |
| 100142 | GEL | Female 77 | 3 | 17MAY2018 | Yes | None | None | None |
| . | . | . | 4 | 23MAY2018 | Yes | None | None | None |
| . | . | . | 5 | 31MAY2018 | Yes | None | None | None |
| 100143 | GEL | Male 74 | 3 | 21JUN2018 | Yes | None | None | None |
| . | . | . | 4 | 27JUN2018 | Yes | None | None | None |
| . | . | . | 5 | 04JUL2018 | Yes | None | None | None |
| 100144 | DROP | Female 89 | 3 | 28JUN2018 | Yes | None | None | None |
| . | . | . | 4 | 04JUL2018 | Yes | None | None | None |
| . | . | . | 5 | 12JUL2018 | Yes | None | None | None |
| 100145 | GEL | Male 81 | 3 | 05JUL2018 | Yes | None | None | None |
| . | . | . | 4 | 11JUL2018 | Yes | None | None | None |
| . | . | . | 5 | 18JUL2018 | Yes | None | None | None |
| 100146 | GEL | Male 71 | 3 | 22AUG2018 | Yes | None | None | None |
| . | . | . | 4 | 29AUG2018 | Yes | None | None | None |
| . | . | . | 5 | 06SEP2018 | Yes | None | None | None |
| 100147 | DROP | Male 48 | 3 | 29AUG2018 | Yes | None | None | None |
| . | . | . | 4 | 20SEP2018 | Yes | None | None | None |
| 100148 | DROP | Female 83 | 3 | 31AUG2018 | Yes | None | None | None |
| . | . | . | 4 | 06SEP2018 | Yes | None | None | None |
| . | . | . | 5 | 13SEP2018 | Yes | None | None | None |
| 100149 | DROP | Female 71 | 3 | 31AUG2018 | Yes | None | None | None |
| . | . | . | 4 | 06SEP2018 | Yes | None | None | None |
| . | . | . | 5 | 15SEP2018 | Yes | None | None | None |
| 100150 | GEL | Female 77 | 3 | 06SEP2018 | Yes | None | None | None |
| . | . | . | 4 | 12SEP2018 | Yes | None | None | None |
| . | . | . | 5 | 21SEP2018 | Yes | None | None | None |
| 100151 | DROP | Female 67 | 3 | 05OCT2018 | Yes | None | None | None |
| . | . | . | 4 | 12OCT2018 | Yes | None | None | None |
| . | . | . | 5 | 20OCT2018 | Yes | None | None | None |
| 100152 | GEL | Female 78 | 3 | 05OCT2018 | Yes | None | None | None |
| . | . | . | 4 | 12OCT2018 | Yes | None | None | Mild |
| . | . | . | 5 | 20OCT2018 | Yes | None | None | None |

Listing 14 (6 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Perfomed? | | | Blurred vision | Global subjective tolerability |
|-------------|---------------|-------------------|--------------|-----------|---------|----------|-------------------|--------------------------------------|
| | | | | Date | Burning | Stinging | | |
| 100153 | DROP | Female 81 | 3 | 18OCT2018 | Yes | None | None | None |
| | | | 4 | 24OCT2018 | Yes | None | None | None |
| | | | 5 | 29OCT2018 | Yes | None | None | None |
| 100154 | GEL | Female 68 | 3 | 19OCT2018 | Yes | None | None | None |
| | | | 4 | 26OCT2018 | Yes | None | None | None |
| | | | 5 | 02NOV2018 | Yes | None | None | None |
| 100155 | DROP | Female 79 | 3 | 19OCT2018 | Yes | None | None | None |
| | | | 4 | 26OCT2018 | Yes | None | None | None |
| | | | 5 | 02NOV2018 | Yes | None | None | None |
| 100156 | GEL | Female 69 | 3 | 19OCT2018 | Yes | None | None | None |
| | | | 4 | 26OCT2018 | Yes | None | None | None |
| | | | 5 | 02NOV2018 | Yes | None | None | None |
| 100201 | GEL | Female 80 | 3 | 09DEC2017 | Yes | None | Mild | None |
| | | | 4 | 13DEC2017 | Yes | None | None | None |
| | | | 5 | 22DEC2017 | Yes | None | None | None |
| 100202 | DROP | Female 70 | 3 | 09DEC2017 | Yes | None | None | None |
| | | | 4 | 14DEC2017 | Yes | None | None | None |
| | | | 5 | 20DEC2017 | Yes | None | None | None |
| 100203 | DROP | Female 76 | 3 | 15DEC2017 | Yes | None | None | None |
| | | | 4 | 20DEC2017 | Yes | None | None | None |
| | | | 5 | 28DEC2017 | Yes | None | None | None |
| 100204 | GEL | Male 71 | 3 | 15DEC2017 | Yes | None | None | None |
| | | | 4 | 20DEC2017 | Yes | None | None | None |
| | | | 5 | 28DEC2017 | Yes | None | None | None |
| 100205 | GEL | Male 75 | 3 | 09FEB2018 | Yes | None | None | None |
| | | | 4 | 14FEB2018 | Yes | None | None | None |
| | | | 5 | 21FEB2018 | Yes | None | None | None |
| 100206 | DROP | Female 81 | 3 | 12JAN2018 | Yes | None | Mild | None |
| | | | 4 | 18JAN2018 | Yes | None | Mild | None |
| | | | 5 | 24JAN2018 | Yes | None | Mild | None |

Listing 14 (7 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Perfomed? | | | Blurred vision | Global subjective tolerability |
|-------------|---------------|-------------------|--------------|-----------|---------|----------|-------------------|--------------------------------------|
| | | | | Date | Burning | Stinging | | |
| 100207 | DROP | Female 65 | 3 | 12JAN2018 | Yes | None | None | None |
| | | | 4 | 18JAN2018 | Yes | None | None | None |
| | | | 5 | 24JAN2018 | Yes | None | None | None |
| 100208 | GEL | Female 79 | 3 | 12JAN2018 | Yes | None | Mild | None |
| | | | 4 | 18JAN2018 | Yes | None | Mild | None |
| | | | 5 | 31JAN2018 | Yes | None | Mild | None |
| 100210 | DROP | Female 70 | 3 | 19JAN2018 | Yes | None | None | None |
| | | | 4 | 24JAN2018 | Yes | None | None | None |
| | | | 5 | 31JAN2018 | Yes | None | None | None |
| 100211 | GEL | Male 67 | 3 | 19JAN2018 | Yes | None | Mild | None |
| | | | 4 | 24JAN2018 | Yes | None | Mild | None |
| | | | 5 | 31JAN2018 | Yes | None | None | None |
| 100212 | DROP | Female 82 | 3 | 19JAN2018 | Yes | None | None | None |
| | | | 4 | 24JAN2018 | Yes | None | None | None |
| | | | 5 | 31JAN2018 | Yes | None | Mild | None |
| 100213 | DROP | Female 81 | 3 | 02FEB2018 | Yes | None | None | None |
| | | | 4 | 07FEB2018 | Yes | None | None | None |
| | | | 5 | 16FEB2018 | Yes | None | None | None |
| 100214 | DROP | Female 77 | 3 | 09FEB2018 | Yes | None | None | None |
| | | | 4 | 14FEB2018 | Yes | None | None | None |
| | | | 5 | 21FEB2018 | Yes | None | None | None |
| 100215 | GEL | Female 83 | 3 | 09FEB2018 | Yes | None | None | None |
| | | | 4 | 14FEB2018 | Yes | None | None | None |
| | | | 5 | 21FEB2018 | Yes | None | None | None |
| 100216 | GEL | Female 74 | 3 | 16FEB2018 | Yes | None | None | None |
| | | | 4 | 21FEB2018 | Yes | None | None | None |
| | | | 5 | 28FEB2018 | Yes | None | None | None |
| 100217 | DROP | Female 72 | 3 | 09MAR2018 | Yes | None | None | None |
| | | | 4 | 14MAR2018 | Yes | None | None | None |
| | | | 5 | 21MAR2018 | Yes | None | None | None |

Listing 14 (8 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Date | Global | | | | | |
|-------------|---------------|---------------|--------------|-----------|------------|---------|----------|----------------------------|------|------|
| | | | | | Performed? | Burning | Stinging | subjective tolerability | | |
| 100218 | DROP | Male | 72 | 3 | 09MAR2018 | Yes | None | Mild | None | None |
| . | . | . | 4 | 14MAR2018 | Yes | None | Mild | None | None | |
| . | . | . | 5 | 21MAR2018 | Yes | None | Mild | None | None | |
| 100219 | GEL | Female | 83 | 3 | 16MAR2018 | Yes | Mild | None | None | None |
| . | . | . | 4 | 21MAR2018 | Yes | None | None | None | None | |
| . | . | . | 5 | 28MAR2018 | Yes | None | Mild | None | None | |
| 100220 | GEL | Male | 64 | 3 | 16MAR2018 | Yes | None | None | None | None |
| . | . | . | 4 | 21MAR2018 | Yes | None | None | None | None | |
| . | . | . | 5 | 28MAR2018 | Yes | None | None | None | None | |
| 100221 | GEL | Female | 76 | 3 | 06APR2018 | Yes | None | None | None | None |
| . | . | . | 4 | 11APR2018 | Yes | None | None | None | None | |
| . | . | . | 5 | 20APR2018 | Yes | None | None | None | None | |
| 100222 | DROP | Female | 76 | 3 | 13APR2018 | Yes | None | None | None | None |
| . | . | . | 4 | 18APR2018 | Yes | None | None | None | None | |
| . | . | . | 5 | 26APR2018 | Yes | None | None | None | None | |
| 100223 | DROP | Male | 61 | 3 | 13APR2018 | Yes | None | None | None | None |
| . | . | . | 4 | 18APR2018 | Yes | None | None | None | None | |
| . | . | . | 5 | 26APR2018 | Yes | None | None | None | None | |
| 100224 | GEL | Female | 75 | 3 | 27APR2018 | Yes | None | None | None | None |
| . | . | . | 4 | 02MAY2018 | Yes | None | None | None | None | |
| . | . | . | 5 | 09MAY2018 | Yes | None | None | None | None | |
| 100225 | DROP | Female | 79 | 3 | 27APR2018 | Yes | None | None | None | None |
| . | . | . | 4 | 02MAY2018 | Yes | None | None | None | None | |
| . | . | . | 5 | 09MAY2018 | Yes | None | None | None | None | |
| 100226 | GEL | Female | 74 | 3 | 27APR2018 | Yes | None | None | None | None |
| . | . | . | 4 | 02MAY2018 | Yes | None | None | None | None | |
| . | . | . | 5 | 09MAY2018 | Yes | None | None | None | None | |
| 100227 | DROP | Female | 68 | 3 | 04MAY2018 | Yes | None | None | None | None |
| . | . | . | 4 | 09MAY2018 | Yes | None | None | None | None | |
| . | . | . | 5 | 16MAY2018 | Yes | None | None | None | None | |
| 100228 | GEL | Female | 68 | 3 | 04MAY2018 | Yes | None | None | None | None |
| . | . | . | 4 | 09MAY2018 | Yes | None | None | None | None | |

Listing 14 (9 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Perfomed? | | | Blurred vision | Global subjective tolerability |
|-------------|---------------|-------------------|--------------|-----------|---------|----------|-------------------|--------------------------------------|
| | | | | Date | Burning | Stinging | | |
| 100229 | GEL | Female 70 | 3 | 11MAY2018 | Yes | None | None | None |
| | | | 4 | 16MAY2018 | Yes | None | None | None |
| | | | 5 | 23MAY2018 | Yes | None | None | None |
| 100230 | GEL | Female 63 | 3 | 11MAY2018 | Yes | None | None | None |
| | | | 4 | 16MAY2018 | Yes | None | None | None |
| | | | 5 | 23MAY2018 | Yes | None | None | None |
| 100231 | DROP | Female 74 | 3 | 11MAY2018 | Yes | None | None | None |
| | | | 4 | 16MAY2018 | Yes | None | None | None |
| | | | 5 | 23MAY2018 | Yes | None | None | None |
| 100232 | DROP | Female 73 | 3 | 11MAY2018 | Yes | None | None | None |
| | | | 4 | 16MAY2018 | Yes | None | None | None |
| | | | 5 | 23MAY2018 | Yes | None | None | None |
| 100233 | GEL | Female 72 | 3 | 25MAY2018 | Yes | None | None | None |
| | | | 4 | 30MAY2018 | Yes | None | None | None |
| | | | 5 | 06JUN2018 | Yes | None | None | None |
| 100234 | GEL | Female 73 | 3 | 25MAY2018 | Yes | None | None | None |
| | | | 4 | 30MAY2018 | Yes | None | None | None |
| | | | 5 | 06JUN2018 | Yes | None | None | None |
| 100235 | DROP | Male 64 | 3 | 01JUN2018 | Yes | None | None | None |
| | | | 4 | 06JUN2018 | Yes | None | None | None |
| | | | 5 | 13JUN2018 | Yes | None | None | None |
| 100236 | DROP | Female 70 | 3 | 01JUN2018 | Yes | None | None | None |
| | | | 4 | 06JUN2018 | Yes | None | None | None |
| | | | 5 | 13JUN2018 | Yes | None | None | None |
| 100237 | DROP | Male 73 | 3 | 08JUN2018 | Yes | None | None | None |
| | | | 4 | 13JUN2018 | Yes | None | None | None |
| | | | 5 | 20JUN2018 | Yes | None | None | None |
| 100238 | GEL | Male 78 | 3 | 08JUN2018 | Yes | None | None | None |
| | | | 4 | 13JUN2018 | Yes | None | None | None |
| | | | 5 | 20JUN2018 | Yes | None | None | None |

Listing 14 (10 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Perfomed? | | | Blurred vision | Global subjective tolerability |
|-------------|---------------|-------------------|--------------|-----------|---------|----------|-------------------|--------------------------------------|
| | | | | Date | Burning | Stinging | | |
| 100239 | DROP | Female 80 | 3 | 15JUN2018 | Yes | None | None | None |
| | | | 4 | 20JUN2018 | Yes | None | None | None |
| | | | 5 | 27JUN2018 | Yes | None | None | None |
| 100241 | GEL | Female 74 | 3 | 26OCT2018 | Yes | None | None | None |
| | | | 4 | 31OCT2018 | Yes | None | None | None |
| | | | 5 | 07NOV2018 | Yes | None | None | None |
| 100242 | GEL | Female 67 | 3 | 09NOV2018 | Yes | None | None | None |
| | | | 4 | 14NOV2018 | Yes | None | None | None |
| | | | 5 | 22NOV2018 | Yes | None | None | None |
| 100243 | DROP | Male 74 | 3 | 07DEC2018 | Yes | None | None | None |
| | | | 4 | 12DEC2018 | Yes | None | None | None |
| | | | 5 | 19DEC2018 | Yes | None | None | None |
| 100244 | GEL | Female 66 | 3 | 14DEC2018 | Yes | None | None | None |
| | | | 4 | 19DEC2018 | Yes | None | None | None |
| | | | 5 | 27DEC2018 | Yes | None | None | None |
| 100245 | DROP | Female 69 | 3 | 14DEC2018 | Yes | None | None | None |
| | | | 4 | 19DEC2018 | Yes | None | None | None |
| | | | 5 | 27DEC2018 | Yes | None | None | None |
| 100301 | GEL | Female 68 | 3 | 20OCT2017 | Yes | None | None | None |
| | | | 4 | 25OCT2017 | Yes | None | None | None |
| | | | 5 | 03NOV2017 | Yes | None | None | None |
| 100302 | GEL | Male 61 | 3 | 03NOV2017 | Yes | None | None | None |
| | | | 4 | 09NOV2017 | Yes | None | None | None |
| | | | 5 | 17NOV2017 | Yes | None | None | None |
| 100303 | DROP | Female 73 | 3 | 03NOV2017 | Yes | None | None | None |
| | | | 4 | 09NOV2017 | Yes | None | None | None |
| | | | 5 | 17NOV2017 | Yes | None | None | None |
| 100304 | DROP | Male 58 | 3 | 17NOV2017 | Yes | None | None | None |
| | | | 4 | 23NOV2017 | Yes | None | None | None |
| | | | 5 | 30NOV2017 | Yes | None | None | None |

Listing 14 (11 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Date | Performed? | | | Blurred vision | Global subjective tolerability |
|-------------|---------------|-------------------|--------------|-----------|------------|----------|------|-------------------|--------------------------------------|
| | | | | | Burning | Stinging | | | |
| 100305 | DROP | Female 85 | 3 | 17NOV2017 | Yes | None | None | None | None |
| | | | 4 | 23NOV2017 | Yes | None | None | None | None |
| | | | 5 | 30NOV2017 | Yes | None | None | None | None |
| 100307 | GEL | Female 73 | 3 | 30NOV2017 | Yes | None | None | None | None |
| | | | 4 | 06DEC2017 | Yes | None | None | None | None |
| | | | 5 | 14DEC2017 | Yes | None | None | None | None |
| 100309 | DROP | Female 61 | 3 | 30NOV2017 | Yes | None | None | None | None |
| | | | 4 | 06DEC2017 | Yes | None | None | None | None |
| | | | 5 | 14DEC2017 | Yes | None | None | None | None |
| 100310 | GEL | Female 73 | 3 | 01DEC2017 | Yes | None | None | None | None |
| | | | 4 | 06DEC2017 | Yes | None | None | None | None |
| | | | 5 | 14DEC2017 | Yes | None | None | None | None |
| 100311 | GEL | Female 83 | 3 | 06DEC2017 | Yes | None | None | None | None |
| | | | 4 | 13DEC2017 | Yes | None | None | None | None |
| | | | 5 | 19DEC2017 | Yes | None | None | None | None |
| 100312 | DROP | Female 71 | 3 | 06DEC2017 | Yes | None | None | None | None |
| | | | 4 | 13DEC2017 | Yes | None | None | None | None |
| | | | 5 | 19DEC2017 | Yes | None | None | None | None |
| 100314 | DROP | Male 67 | 3 | 06DEC2017 | Yes | None | None | None | None |
| | | | 4 | 13DEC2017 | Yes | None | None | None | None |
| | | | 5 | 19DEC2017 | Yes | None | None | None | None |
| 100315 | GEL | Female 65 | 3 | 06DEC2017 | Yes | None | None | None | None |
| | | | 4 | 13DEC2017 | Yes | None | None | None | None |
| | | | 5 | 19DEC2017 | Yes | None | None | None | None |
| 100316 | DROP | Male 76 | 3 | 06DEC2017 | Yes | None | None | None | None |
| | | | 4 | 13DEC2017 | Yes | None | None | None | None |
| | | | 5 | 19DEC2017 | Yes | None | None | None | None |
| 100317 | GEL | Male 85 | 3 | 06DEC2017 | Yes | None | None | None | None |
| | | | 4 | 14DEC2017 | Yes | None | None | None | None |
| | | | 5 | 19DEC2017 | Yes | None | None | None | None |

Listing 14 (12 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Date | Performed? | | | Blurred vision | Global subjective tolerability |
|-------------|---------------|-------------------|--------------|-----------|------------|----------|------|-------------------|--------------------------------------|
| | | | | | Burning | Stinging | | | |
| 100318 | GEL | Female . . . | 80 | 3 | 06DEC2017 | Yes | None | None | None |
| | | | 4 | 13DEC2017 | Yes | None | None | None | None |
| | | | 5 | 19DEC2017 | Yes | None | None | None | None |
| 100319 | DROP | Male . . . | 70 | 3 | 06DEC2017 | Yes | None | Mild | None |
| | | | 4 | 13DEC2017 | Yes | None | None | None | None |
| | | | 5 | 19DEC2017 | Yes | None | None | None | None |
| 100320 | DROP | Male . . . | 69 | 3 | 06DEC2017 | Yes | None | Mild | None |
| | | | 4 | 13DEC2017 | Yes | None | None | None | None |
| | | | 5 | 19DEC2017 | Yes | None | Mild | None | None |
| 100321 | GEL | Male . . . | 72 | 3 | 12DEC2017 | Yes | None | None | None |
| | | | 4 | 27DEC2017 | Yes | None | None | None | None |
| | | | 5 | 27DEC2017 | Yes | None | None | None | None |
| 100322 | GEL | Male . . . | 80 | 3 | 14DEC2017 | Yes | None | Mild | None |
| | | | 4 | 19DEC2017 | Yes | None | None | None | None |
| | | | 5 | 27DEC2017 | Yes | None | None | None | None |
| 100323 | DROP | Female . . . | 76 | 3 | 14DEC2017 | Yes | None | None | None |
| | | | 4 | 19DEC2017 | Yes | None | None | None | None |
| | | | 5 | 27DEC2017 | Yes | None | None | None | None |
| 100324 | DROP | Male . . . | 65 | 3 | 19DEC2017 | Yes | None | None | None |
| | | | 4 | 27DEC2017 | Yes | None | None | None | None |
| | | | 5 | 02JAN2018 | Yes | None | None | None | None |
| 100326 | DROP | Male . . . | 81 | 3 | 19DEC2017 | Yes | None | Mild | None |
| | | | 4 | 27DEC2017 | Yes | None | Mild | None | None |
| | | | 5 | 03JAN2018 | Yes | None | None | None | None |
| 100327 | GEL | Female . . . | 73 | 3 | 19DEC2017 | Yes | None | None | None |
| | | | 4 | 27DEC2017 | Yes | None | None | None | None |
| | | | 5 | 02JAN2018 | Yes | None | None | None | None |
| 100328 | DROP | Male . . . | 82 | 3 | 19DEC2017 | Yes | None | None | None |
| | | | 4 | 27DEC2017 | Yes | None | None | None | None |
| | | | 5 | 02JAN2018 | Yes | None | None | None | None |

Listing 14 (13 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Date | Performed? | | | Blurred vision | Global subjective tolerability |
|-------------|---------------|-------------------|--------------|-------------|------------|----------|------|-------------------|--------------------------------------|
| | | | | | Burning | Stinging | | | |
| 100329 | GEL | Male | 74 | 3 19DEC2017 | Yes | None | None | None | None |
| | | | . | 4 27DEC2017 | Yes | None | None | None | None |
| | | | . | 5 02JAN2018 | Yes | None | None | None | None |
| 100330 | DROP | Male | 61 | 3 20DEC2017 | Yes | None | None | None | None |
| | | | . | 4 27DEC2017 | Yes | None | None | None | None |
| | | | . | 5 03JAN2018 | Yes | None | None | None | None |
| 100331 | GEL | Female | 71 | 3 20DEC2017 | Yes | None | None | None | None |
| | | | . | 4 27DEC2017 | Yes | None | None | None | None |
| | | | . | 5 03JAN2018 | Yes | None | None | None | None |
| 100332 | DROP | Male | 82 | 3 13JAN2018 | Yes | None | None | None | None |
| | | | . | 4 19JAN2018 | Yes | None | None | None | None |
| | | | . | 5 25JAN2018 | Yes | None | None | None | None |
| 100333 | DROP | Male | 62 | 3 26JAN2018 | Yes | None | None | None | None |
| | | | . | 4 01FEB2018 | Yes | None | None | None | None |
| | | | . | 5 09FEB2018 | Yes | None | None | None | None |
| 100334 | GEL | Male | 72 | 3 25JAN2018 | Yes | None | None | None | None |
| | | | . | 4 01FEB2018 | Yes | None | None | None | None |
| | | | . | 5 08FEB2018 | Yes | None | None | None | None |
| 100335 | DROP | Female | 80 | 3 07FEB2018 | Yes | None | None | None | None |
| | | | . | 4 12FEB2018 | Yes | None | None | None | None |
| | | | . | 5 20FEB2018 | Yes | None | None | None | None |
| 100336 | GEL | Female | 82 | 3 07MAR2018 | Yes | None | None | None | None |
| | | | . | 4 12MAR2018 | Yes | None | None | None | None |
| | | | . | 5 20MAR2018 | Yes | None | None | None | None |
| 100338 | DROP | Female | 87 | 3 22MAR2018 | Yes | None | None | None | None |
| | | | . | 4 27MAR2018 | Yes | None | None | None | None |
| | | | . | 5 05APR2018 | Yes | None | None | None | None |
| 100339 | GEL | Male | 56 | 3 29MAR2018 | Yes | None | Mild | None | None |
| | | | . | 4 05APR2018 | Yes | None | None | None | None |
| | | | . | 5 11APR2018 | Yes | None | None | None | None |

Listing 14 (14 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age (year) | Visit No. | Global | | | | |
|-------------|---------------|---------------|--------------|------------|---------|----------|----------------|-------------------------|
| | | | | Performed? | Burning | Stinging | Blurred vision | subjective tolerability |
| 100340 | DROP | Male 83 | 3 13APR2018 | Yes | None | None | None | None |
| . | . | . | 4 19APR2018 | Yes | None | None | None | None |
| . | . | . | 5 26APR2018 | Yes | None | None | None | None |
| 100341 | GEL | Male 88 | 3 13APR2018 | Yes | None | None | None | None |
| . | . | . | 4 19APR2018 | Yes | None | None | None | None |
| . | . | . | 5 26APR2018 | Yes | None | None | None | None |
| 100342 | DROP | Female 86 | 3 13APR2018 | Yes | None | None | None | None |
| . | . | . | 4 19APR2018 | Yes | None | None | None | None |
| . | . | . | 5 26APR2018 | Yes | None | None | None | None |
| 100343 | GEL | Male 74 | 3 11APR2018 | Yes | None | None | None | None |
| . | . | . | 4 17APR2018 | Yes | None | None | None | None |
| . | . | . | 5 24APR2018 | Yes | None | None | None | None |
| 100344 | DROP | Female 68 | 3 11APR2018 | Yes | None | None | None | None |
| . | . | . | 4 17APR2018 | Yes | None | None | None | None |
| . | . | . | 5 23APR2018 | Yes | None | None | None | None |
| 100345 | GEL | Male 48 | 3 11APR2018 | Yes | None | None | None | None |
| . | . | . | 4 17APR2018 | Yes | None | None | None | None |
| . | . | . | 5 23APR2018 | Yes | None | None | None | None |
| 100346 | DROP | Female 77 | 3 13APR2018 | Yes | None | None | None | None |
| . | . | . | 4 19APR2018 | Yes | None | None | None | None |
| . | . | . | 5 26APR2018 | Yes | None | None | None | None |
| 100347 | GEL | Male 58 | 3 19APR2018 | Yes | None | None | None | None |
| . | . | . | 4 24APR2018 | Yes | None | None | None | None |
| . | . | . | 5 02MAY2018 | No | . | . | . | . |
| 100348 | GEL | Female 38 | 3 25APR2018 | Yes | None | None | None | None |
| . | . | . | 4 30APR2018 | Yes | None | None | None | None |
| . | . | . | 5 08MAY2018 | Yes | None | None | None | None |
| 100349 | DROP | Male 71 | 3 25MAY2018 | Yes | None | None | None | None |
| . | . | . | 4 30MAY2018 | Yes | None | None | None | None |
| . | . | . | 5 06JUN2018 | Yes | None | None | None | None |

Listing 14 (15 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Perfomed? | | | Blurred vision | Global subjective tolerability |
|-------------|---------------|-------------------|--------------|-----------|---------|----------|-------------------|--------------------------------------|
| | | | | Date | Burning | Stinging | | |
| 100350 | DROP | Female 67 | 3 | 23MAY2018 | No | . | . | . |
| | | | 4 | 30MAY2018 | Yes | None | None | None |
| | | | 5 | 05JUN2018 | Yes | None | None | None |
| 100351 | GEL | Female 79 | 3 | 26MAY2018 | Yes | None | None | None |
| | | | 4 | 01JUN2018 | Yes | None | None | None |
| | | | 5 | 08JUN2018 | Yes | None | None | None |
| 100352 | DROP | Female 63 | 3 | 30MAY2018 | Yes | None | None | None |
| | | | 4 | 06JUN2018 | Yes | None | None | None |
| | | | 5 | 13JUN2018 | Yes | None | None | None |
| 100353 | GEL | Female 72 | 3 | 08JUN2018 | Yes | None | None | None |
| | | | 4 | 14JUN2018 | Yes | None | None | None |
| | | | 5 | 21JUN2018 | Yes | None | None | None |
| 100354 | GEL | Female 80 | 3 | 08JUN2018 | Yes | None | None | None |
| | | | 4 | 14JUN2018 | Yes | None | None | None |
| | | | 5 | 21JUN2018 | Yes | None | None | None |
| 100355 | DROP | Female 80 | 3 | 14JUN2018 | Yes | None | None | None |
| | | | 4 | 21JUN2018 | Yes | None | None | None |
| | | | 5 | 27JUN2018 | Yes | None | None | None |
| 100356 | GEL | Male 74 | 3 | 19JUN2018 | Yes | None | None | None |
| | | | 4 | 26JUN2018 | Yes | None | None | None |
| | | | 5 | 04JUL2018 | Yes | None | None | None |
| 200101 | GEL | Female 66 | 3 | 17JAN2018 | Yes | None | Mild | Moderate |
| | | | 4 | 24JAN2018 | Yes | None | Mild | Mild |
| | | | 5 | 31JAN2018 | Yes | None | Mild | None |
| 200102 | DROP | Female 76 | 3 | 31JAN2018 | Yes | Mild | Mild | None |
| | | | 4 | 05FEB2018 | Yes | None | None | None |
| | | | 5 | 13FEB2018 | Yes | None | Mild | Mild |
| 200103 | DROP | Male 82 | 3 | 14FEB2018 | Yes | None | None | None |
| | | | 4 | 19FEB2018 | Yes | None | Mild | None |
| | | | 5 | 26FEB2018 | Yes | None | None | None |

Listing 14 (16 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Date | Performed? | | | Blurred vision | Global subjective tolerability |
|-------------|---------------|-------------------|--------------|-----------|------------|----------|----------|-------------------|--------------------------------------|
| | | | | | Burning | Stinging | | | |
| 200104 | GEL | Female 78 | 3 | 09MAY2018 | Yes | None | None | None | None |
| | | | 4 | 16MAY2018 | Yes | None | None | None | None |
| | | | 5 | 23MAY2018 | Yes | None | Mild | None | None |
| 200105 | GEL | Female 65 | 3 | 30MAY2018 | Yes | Mild | Moderate | Mild | None |
| | | | 4 | 06JUN2018 | Yes | None | Mild | Mild | None |
| | | | 5 | 13JUN2018 | Yes | None | None | None | None |
| 200106 | DROP | Female 75 | 3 | 27JUN2018 | Yes | None | None | None | None |
| | | | 4 | 04JUL2018 | Yes | None | None | None | None |
| | | | 5 | 11JUL2018 | Yes | None | None | None | None |
| 200107 | DROP | Female 54 | 3 | 04JUL2018 | Yes | Severe | Severe | Mild | Severe |
| 200108 | GEL | Male 77 | 3 | 05SEP2018 | Yes | Mild | None | None | None |
| | | | 4 | 12SEP2018 | Yes | Mild | None | Mild | None |
| | | | 5 | 20SEP2018 | Yes | None | None | Severe | Moderate |
| 200109 | GEL | Female 84 | 3 | 03OCT2018 | Yes | Mild | Mild | Moderate | Mild |
| | | | 4 | 10OCT2018 | No | . | . | . | . |
| 200110 | DROP | Male 64 | 3 | 10OCT2018 | Yes | None | None | None | None |
| | | | 4 | 17OCT2018 | Yes | None | Mild | Mild | None |
| | | | 5 | 23OCT2018 | Yes | None | None | Mild | None |
| 200111 | GEL | Male 73 | 3 | 07NOV2018 | Yes | None | None | None | None |
| | | | 4 | 14NOV2018 | Yes | None | Mild | Moderate | None |
| | | | 5 | 21NOV2018 | Yes | None | None | Mild | None |
| 200112 | DROP | Male 85 | 3 | 14NOV2018 | Yes | Mild | None | None | None |
| | | | 4 | 21NOV2018 | Yes | None | None | Mild | None |
| | | | 5 | 28NOV2018 | Yes | None | None | Mild | None |
| 200113 | DROP | Male 77 | 3 | 14NOV2018 | Yes | None | None | None | None |
| | | | 4 | 21NOV2018 | Yes | None | None | None | None |
| | | | 5 | 29NOV2018 | Yes | None | None | None | None |
| 200115 | GEL | Female 70 | 3 | 19DEC2018 | Yes | None | None | None | None |
| | | | 4 | 27DEC2018 | Yes | None | None | None | None |
| | | | 5 | 03JAN2019 | Yes | None | None | None | None |

Listing 14 (17 of 17): Evaluation of global tolerability by the investigator during the study

| Sbj Code | Study drug | Age Sex (year) | Visit No. | Global | | | subjective tolerability | | | |
|-------------|---------------|-------------------|--------------|--------|------------|--------|----------------------------|------|------|------|
| | | | | Date | Performed? | Burned | | | | |
| 200202 | DROP | Female | 71 | 3 | 19JUN2018 | Yes | None | None | None | None |
| | | | . | 4 | 25JUN2018 | Yes | None | None | None | None |
| | | | . | 5 | 03JUL2018 | Yes | None | None | None | None |
| 200203 | GEL | Male | 66 | 3 | 27JUN2018 | Yes | None | None | None | None |
| | | | . | 4 | 02JUL2018 | Yes | None | None | Mild | None |
| | | | . | 5 | 12JUL2018 | Yes | None | None | None | None |
| 200204 | GEL | Male | 58 | 3 | 04JUL2018 | Yes | None | None | None | None |
| | | | . | 4 | 10JUL2018 | Yes | None | None | None | None |
| | | | . | 5 | 18JUL2018 | Yes | None | None | None | None |

SAS program: L03_List_14.sas - SAS dataset name(s): RAND,DEMOGRAPHY,TOLERABILITY

Listing 15 (1 of 9): End of study

| Sbj | Study | Age | Last visit | Study completed | Reason for withdrawal | Random code broken | | |
|--------|-------|--------|------------|-----------------|-----------------------|--------------------|------|--------|
| Code | drug | Sex | (year) | Date | N/Y | N/Y | Date | Reason |
| 100101 | DROP | Female | 84 | 27DEC2017 | Yes . | NO | . | |
| 100102 | GEL | Male | 80 | 29DEC2017 | Yes . | NO | . | |
| 100103 | | Female | 70 | 27OCT2017 | No Adverse event | NO | . | |
| 100104 | GEL | Male | 70 | 05JAN2018 | Yes . | NO | . | |
| 100105 | DROP | Female | 85 | 08JAN2018 | Yes . | NO | . | |
| 100106 | GEL | Male | 56 | 15JAN2018 | Yes . | NO | . | |
| 100107 | DROP | Female | 82 | 26JAN2018 | Yes . | NO | . | |
| 100108 | DROP | Female | 73 | 06FEB2018 | Yes . | NO | . | |
| 100109 | GEL | Female | 56 | 12FEB2018 | Yes . | NO | . | |
| 100110 | DROP | Female | 75 | 12FEB2018 | Yes . | NO | . | |
| 100111 | DROP | Female | 60 | 12FEB2018 | Yes . | NO | . | |
| 100112 | GEL | Male | 73 | 05MAR2018 | Yes . | NO | . | |
| 100113 | GEL | Female | 77 | 05MAR2018 | Yes . | NO | . | |
| 100114 | GEL | Male | 64 | 05MAR2018 | Yes . | NO | . | |
| 100115 | DROP | Male | 76 | 06MAR2018 | Yes . | NO | . | |
| 100116 | GEL | Male | 62 | 06MAR2018 | Yes . | NO | . | |
| 100117 | DROP | Female | 51 | 12MAR2018 | Yes . | NO | . | |
| 100118 | DROP | Female | 78 | 19MAR2018 | Yes . | NO | . | |
| 100119 | DROP | Female | 72 | 26MAR2018 | Yes . | NO | . | |
| 100120 | GEL | Male | 79 | 26MAR2018 | Yes . | NO | . | |
| 100121 | GEL | Male | 80 | 26MAR2018 | Yes . | NO | . | |

Listing 15 (2 of 9): End of study

| Sbj | Study | Age | Last visit | Study completed | Reason for withdrawal | Random code broken | | |
|--------|-------|--------|------------|-----------------|-----------------------|--------------------|------|--------|
| Code | drug | Sex | (year) | Date | N/Y | N/Y | Date | Reason |
| 100122 | DROP | Female | 76 | 27MAR2018 | Yes . | NO | . | |
| 100123 | DROP | Female | 76 | 27MAR2018 | Yes . | NO | . | |
| 100124 | GEL | Female | 71 | 03APR2018 | Yes . | NO | . | |
| 100125 | GEL | Female | 62 | 03APR2018 | Yes . | NO | . | |
| 100126 | GEL | Female | 85 | 09APR2018 | Yes . | NO | . | |
| 100127 | GEL | Female | 68 | 10APR2018 | Yes . | NO | . | |
| 100128 | DROP | Male | 80 | 10APR2018 | Yes . | NO | . | |
| 100129 | DROP | Female | 78 | 10APR2018 | Yes . | NO | . | |
| 100130 | GEL | Male | 66 | 23APR2018 | Yes . | NO | . | |
| 100131 | DROP | Female | 77 | 23APR2018 | Yes . | NO | . | |
| 100132 | DROP | Male | 69 | 08MAY2018 | Yes . | NO | . | |
| 100133 | GEL | Male | 74 | 08MAY2018 | Yes . | NO | . | |
| 100134 | DROP | Female | 66 | 08MAY2018 | Yes . | NO | . | |
| 100135 | GEL | Male | 69 | 15MAY2018 | Yes . | NO | . | |
| 100136 | GEL | Female | 90 | 06JUN2018 | Yes . | NO | . | |
| 100137 | DROP | Female | 62 | 19JUN2018 | Yes . | NO | . | |
| 100138 | GEL | Male | 63 | 19JUN2018 | Yes . | NO | . | |
| 100139 | DROP | Female | 71 | 26JUN2018 | Yes . | NO | . | |
| 100140 | GEL | Male | 81 | 02JUL2018 | Yes . | NO | . | |
| 100141 | DROP | Female | 74 | 02JUL2018 | Yes . | NO | . | |
| 100142 | GEL | Female | 77 | 16JUL2018 | Yes . | NO | . | |

Listing 15 (3 of 9): End of study

| Sbj | Study | Age | Last visit | Study completed | Reason for withdrawal | Random code broken | | |
|--------|-------|--------|------------|-----------------|---|--------------------|------|--------|
| Code | drug | Sex | (year) | Date | N/Y | N/Y | Date | Reason |
| 100143 | GEL | Male | 74 | 20AUG2018 | Yes . | NO | . | |
| 100144 | DROP | Female | 89 | 27AUG2018 | Yes . | NO | . | |
| 100145 | GEL | Male | 81 | 04SEP2018 | Yes . | NO | . | |
| 100146 | GEL | Male | 71 | 22OCT2018 | Yes . | NO | . | |
| 100147 | DROP | Male | 48 | 04SEP2018 | No Withdrawal of consent/Patient choice | NO | . | |
| 100148 | DROP | Female | 83 | 29OCT2018 | Yes . | NO | . | |
| 100149 | DROP | Female | 71 | 29OCT2018 | Yes . | NO | . | |
| 100150 | GEL | Female | 77 | 05NOV2018 | Yes . | NO | . | |
| 100151 | DROP | Female | 67 | 04DEC2018 | Yes . | NO | . | |
| 100152 | GEL | Female | 78 | 20OCT2018 | No Withdrawal of consent/Patient choice | NO | . | |
| 100153 | DROP | Female | 81 | 18DEC2018 | Yes . | NO | . | |
| 100154 | GEL | Female | 68 | 18DEC2018 | Yes . | NO | . | |
| 100155 | DROP | Female | 79 | 18DEC2018 | Yes . | NO | . | |
| 100156 | GEL | Female | 69 | 18DEC2018 | Yes . | NO | . | |
| 100201 | GEL | Female | 80 | 08FEB2018 | Yes . | NO | . | |
| 100202 | DROP | Female | 70 | 08FEB2018 | Yes . | NO | . | |
| 100203 | DROP | Female | 76 | 15FEB2018 | Yes . | NO | . | |
| 100204 | GEL | Male | 71 | 15FEB2018 | Yes . | NO | . | |
| 100205 | GEL | Male | 75 | 09APR2018 | Yes . | NO | . | |
| 100206 | DROP | Female | 81 | 14MAR2018 | Yes . | NO | . | |
| 100207 | DROP | Female | 65 | 14MAR2018 | Yes . | NO | . | |

Listing 15 (4 of 9): End of study

| Sbj | Study | Age | Last visit | Study completed | Reason for withdrawal | Random code broken | | |
|--------|-------|--------|------------|-----------------|---|--------------------|------|--------|
| Code | drug | Sex | (year) | Date | N/Y | N/Y | Date | Reason |
| 100208 | GEL | Female | 79 | 14MAR2018 | Yes . | NO | . | |
| 100209 | GEL | Female | 77 | 18JAN2018 | No Withdrawal of consent/Patient choice | NO | . | |
| 100210 | DROP | Female | 70 | 22MAR2018 | Yes . | NO | . | |
| 100211 | GEL | Male | 67 | 22MAR2018 | Yes . | NO | . | |
| 100212 | DROP | Female | 82 | 22MAR2018 | Yes . | NO | . | |
| 100213 | DROP | Female | 81 | 04APR2018 | Yes . | NO | . | |
| 100214 | DROP | Female | 77 | 09APR2018 | Yes . | NO | . | |
| 100215 | GEL | Female | 83 | 09APR2018 | Yes . | NO | . | |
| 100216 | GEL | Female | 74 | 16APR2018 | Yes . | NO | . | |
| 100217 | DROP | Female | 72 | 08MAY2018 | Yes . | NO | . | |
| 100218 | DROP | Male | 72 | 08MAY2018 | Yes . | NO | . | |
| 100219 | GEL | Female | 83 | 16MAY2018 | Yes . | NO | . | |
| 100220 | GEL | Male | 64 | 16MAY2018 | Yes . | NO | . | |
| 100221 | GEL | Female | 76 | 01JUN2018 | Yes . | NO | . | |
| 100222 | DROP | Female | 76 | 14JUN2018 | Yes . | NO | . | |
| 100223 | DROP | Male | 61 | 14JUN2018 | Yes . | NO | . | |
| 100224 | GEL | Female | 75 | 27JUN2018 | Yes . | NO | . | |
| 100225 | DROP | Female | 79 | 27JUN2018 | Yes . | NO | . | |
| 100226 | GEL | Female | 74 | 27JUN2018 | Yes . | NO | . | |
| 100227 | DROP | Female | 68 | 04JUL2018 | Yes . | NO | . | |
| 100228 | GEL | Female | 68 | 09MAY2018 | No Withdrawal of consent/Patient choice | NO | . | |

Listing 15 (5 of 9): End of study

| Sbj | Study | Age | Last visit | Study completed | Reason for withdrawal | | Random code broken |
|--------|-------|--------|------------|-----------------|-----------------------|--------------------------------------|--------------------|
| Code | drug | Sex | (year) | Date | N/Y | | N/Y Date Reason |
| 100229 | GEL | Female | 70 | 10JUL2018 | Yes | . | NO . |
| 100230 | GEL | Female | 63 | 11JUL2018 | Yes | . | NO . |
| 100231 | DROP | Female | 74 | 06JUL2018 | Yes | . | NO . |
| 100232 | DROP | Female | 73 | 06JUL2018 | Yes | . | NO . |
| 100233 | GEL | Female | 72 | 20JUL2018 | Yes | . | NO . |
| 100234 | GEL | Female | 73 | 20JUL2018 | Yes | . | NO . |
| 100235 | DROP | Male | 64 | 01AUG2018 | Yes | . | NO . |
| 100236 | DROP | Female | 70 | 01AUG2018 | Yes | . | NO . |
| 100237 | DROP | Male | 73 | 06AUG2018 | Yes | . | NO . |
| 100238 | GEL | Male | 78 | 06AUG2018 | Yes | . | NO . |
| 100239 | DROP | Female | 80 | 14AUG2018 | Yes | . | NO . |
| 100240 | | Female | 72 | 07JUL2018 | No | Withdrawal of consent/Patient choice | NO . |
| 100241 | GEL | Female | 74 | 24DEC2018 | Yes | . | NO . |
| 100242 | GEL | Female | 67 | 12JAN2019 | Yes | . | NO . |
| 100243 | DROP | Male | 74 | 04FEB2019 | Yes | . | NO . |
| 100244 | GEL | Female | 66 | 08FEB2019 | Yes | . | NO . |
| 100245 | DROP | Female | 69 | 08FEB2019 | Yes | . | NO . |
| 100301 | GEL | Female | 68 | 20DEC2017 | Yes | . | NO . |
| 100302 | GEL | Male | 61 | 05JAN2017 | Yes | . | NO . |
| 100303 | DROP | Female | 73 | 05JAN2018 | Yes | . | NO . |
| 100304 | DROP | Male | 58 | 16JAN2018 | Yes | . | NO . |

Listing 15 (6 of 9): End of study

| Sbj | Study | Age | Last visit | Study completed | Reason for withdrawal | Random | code broken |
|--------|-------|--------|------------|-----------------|--|--------|-------------|
| Code | drug | Sex | (year) | Date | N/Y | | |
| 100305 | DROP | Female | 85 | 16JAN2017 | Yes . | NO | . |
| 100306 | DROP | Female | 84 | 22NOV2017 | No Withdrawal of consent/Patient choice | NO | . |
| 100307 | GEL | Female | 73 | 29JAN2018 | Yes . | NO | . |
| 100308 | GEL | Female | 85 | 29NOV2017 | No Withdrawal of consent/Patient choice | NO | . |
| 100309 | DROP | Female | 61 | 29JAN2018 | Yes . | NO | . |
| 100310 | GEL | Female | 73 | 29JAN2018 | Yes . | NO | . |
| 100311 | GEL | Female | 83 | 01FEB2018 | Yes . | NO | . |
| 100312 | DROP | Female | 71 | 01FEB2018 | Yes . | NO | . |
| 100313 | GEL | Male | 71 | 04DEC2017 | No Major complications during cataract surgery | NO | . |
| 100314 | DROP | Male | 67 | 01FEB2017 | Yes . | NO | . |
| 100315 | GEL | Female | 65 | 01FEB2018 | Yes . | NO | . |
| 100316 | DROP | Male | 76 | 01FEB2018 | Yes . | NO | . |
| 100317 | GEL | Male | 85 | 01FEB2018 | Yes . | NO | . |
| 100318 | GEL | Female | 80 | 01FEB2018 | Yes . | NO | . |
| 100319 | DROP | Male | 70 | 01FEB2018 | Yes . | NO | . |
| 100320 | DROP | Male | 69 | 01FEB2018 | Yes . | NO | . |
| 100321 | GEL | Male | 72 | 05FEB2018 | Yes . | NO | . |
| 100322 | GEL | Male | 80 | 12FEB2018 | Yes . | NO | . |
| 100323 | DROP | Female | 76 | 12FEB2018 | Yes . | NO | . |
| 100324 | DROP | Male | 65 | 20FEB2018 | Yes . | NO | . |
| 100325 | GEL | Female | 83 | 18DEC2017 | No Withdrawal of consent/Patient choice | NO | . |

Listing 15 (7 of 9): End of study

| Sbj | Study | Age | Last visit | Study completed | Reason for withdrawal | Random code broken | | |
|--------|-------|--------|------------|-----------------|---|--------------------|------|--------|
| Code | drug | Sex | (year) | Date | N/Y | N/Y | Date | Reason |
| 100326 | DROP | Male | 81 | 16FEB2018 | Yes . | NO | . | |
| 100327 | GEL | Female | 73 | 16FEB2018 | Yes . | NO | . | |
| 100328 | DROP | Male | 82 | 16FEB2018 | Yes . | NO | . | |
| 100329 | GEL | Male | 74 | 16FEB2018 | Yes . | NO | . | |
| 100330 | DROP | Male | 61 | 19FEB2018 | Yes . | NO | . | |
| 100331 | GEL | Female | 71 | 19FEB2018 | Yes . | NO | . | |
| 100332 | DROP | Male | 82 | 12MAR2018 | Yes . | NO | . | |
| 100333 | DROP | Male | 62 | 26MAR2018 | Yes . | NO | . | |
| 100334 | GEL | Male | 72 | 26MAR2018 | Yes . | NO | . | |
| 100335 | DROP | Female | 80 | 05APR2018 | Yes . | NO | . | |
| 100336 | GEL | Female | 82 | 02MAY2018 | Yes . | NO | . | |
| 100337 | GEL | Male | 72 | 10MAR2018 | No Withdrawal of consent/Patient choice | NO | . | |
| 100338 | DROP | Female | 87 | 21MAY2018 | Yes . | NO | . | |
| 100339 | GEL | Male | 56 | 28MAY2018 | Yes . | NO | . | |
| 100340 | DROP | Male | 83 | 12JUN2018 | Yes . | NO | . | |
| 100341 | GEL | Male | 88 | 12JUN2018 | Yes . | NO | . | |
| 100342 | DROP | Female | 86 | 12JUN2018 | Yes . | NO | . | |
| 100343 | GEL | Male | 74 | 11JUN2018 | Yes . | NO | . | |
| 100344 | DROP | Female | 68 | 11JUN2018 | Yes . | NO | . | |
| 100345 | GEL | Male | 48 | 11JUN2018 | Yes . | NO | . | |
| 100346 | DROP | Female | 77 | 12JUN2018 | Yes . | NO | . | |

Listing 15 (8 of 9): End of study

| Sbj | Study | Age | Last visit | Study completed | Reason for withdrawal | | Random code broken |
|--------|-------|--------|------------|-----------------|-----------------------|---------------|--------------------|
| Code | drug | Sex | (year) | Date | N/Y | | N/Y Date Reason |
| 100347 | GEL | Male | 58 | 18JUN2018 | Yes | . | NO . |
| 100348 | GEL | Female | 38 | 25JUN2018 | Yes | . | NO . |
| 100349 | DROP | Male | 71 | 25JUL2018 | Yes | . | NO . |
| 100350 | DROP | Female | 67 | 23JUL2018 | Yes | . | NO . |
| 100351 | GEL | Female | 79 | 25JUL2018 | Yes | . | NO . |
| 100352 | DROP | Female | 63 | 30JUL2018 | Yes | . | NO . |
| 100353 | GEL | Female | 72 | 31JUL2018 | Yes | . | NO . |
| 100354 | GEL | Female | 80 | 07AUG2018 | Yes | . | NO . |
| 100355 | DROP | Female | 80 | 13AUG2018 | Yes | . | NO . |
| 100356 | GEL | Male | 74 | 20AUG2018 | Yes | . | NO . |
| 200101 | GEL | Female | 66 | 19MAR2018 | Yes | . | NO . |
| 200102 | DROP | Female | 76 | 28MAR2018 | Yes | . | NO . |
| 200103 | DROP | Male | 82 | 16APR2018 | Yes | . | NO . |
| 200104 | GEL | Female | 78 | 06JUL2018 | Yes | . | NO . |
| 200105 | GEL | Female | 65 | 23JUN2018 | Yes | . | NO . |
| 200106 | DROP | Female | 75 | 22AUG2018 | Yes | . | NO . |
| 200107 | DROP | Female | 54 | 05JUL2018 | No | Adverse event | NO . |
| 200108 | GEL | Male | 77 | 05NOV2018 | Yes | . | NO . |
| 200109 | GEL | Female | 84 | 10OCT2018 | No | Adverse event | NO . |
| 200110 | DROP | Male | 64 | 05DEC2018 | Yes | . | NO . |
| 200111 | GEL | Male | 73 | 02JAN2019 | Yes | . | NO . |

Listing 15 (9 of 9): End of study

| Sbj | Study | Age | Last visit | Study completed | Reason for withdrawal | Random | code broken |
|--------|-------|--------|------------|-----------------|---|--------|-------------|
| Code | drug | Sex | (year) | Date | N/Y | | |
| 200112 | DROP | Male | 85 | 09JAN2019 | Yes . | NO | . |
| 200113 | DROP | Male | 77 | 11JAN2019 | Yes . | NO | . |
| 200114 | DROP | Female | 64 | 28NOV2018 | No Protocol violation, including disallowed concomitant therapy | NO | . |
| 200115 | GEL | Female | 70 | 13FEB2019 | Yes . | NO | . |
| 200201 | | Female | 71 | 24JAN2018 | No Protocol violation, including disallowed concomitant therapy | # | . |
| 200202 | DROP | Female | 71 | 17AUG2018 | Yes . | NO | . |
| 200203 | GEL | Male | 66 | 04SEP2018 | Yes . | NO | . |
| 200204 | GEL | Male | 58 | 04SEP2018 | Yes . | NO | . |

SAS program: L03_List_15.sas - SAS dataset name(s): RAND,DEMOGRAPHY, EOS

Listing 16 (1 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | | | | |
|-------------|---------------|---------------|---|-------------------------------------|---------|--------|-------|-------|-------|
| | | | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
| 100101 | DROP | Female 84 | RAMIPRIL CPS CARDIOVASCULAR SYSTEM RAMIPRIL ARTERIAL HYPERTENSION | 4FEB2003 | YES | 2.5 mg | 1 | DAILY | ORAL |
| 100105 | DROP | Female 85 | LOBIVON CARDIOVASCULAR SYSTEM NEBIVOLOL ARTERIAL HYPERTENSION | 8FEB2002 | YES | 5 | mg | DAILY | ORAL |
| 100106 | GEL | Male 56 | CANDESARTAN CARDIOVASCULAR SYSTEM CANDESARTAN ARTERIAL HYPERTENSION | 2APR2012 | YES | 4 | mg | DAILY | ORAL |
| | | | LEVOTIROXIN SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONE LEVOTHYROXINE POST- THYROIDECTOMY ADMINISTRATION | 6MAY2004 | YES | 25 | mg | DAILY | ORAL |
| 100110 | DROP | Female 75 | LOBIDIUR (NEBIVOLOL+IDROCLOROTIAZIDE) CARDIOVASCULAR SYSTEM NEBICARD-H ARTERIAL HYPERTENSION | FEB2007 | YES | 5 + 12 | mg | DAILY | ORAL |
| 100112 | GEL | Male 73 | RAMIPRIL CARDIOVASCULAR SYSTEM RAMIPRIL ARTERIAL HYPERTENSION | 20APR2005 | YES | 5 | mg | DAILY | ORAL |
| 100113 | GEL | Female 77 | LISINOPRIL CARDIOVASCULAR SYSTEM LISINOPRIL ARTERIAL HYPERTENSION | 7OCT2013 | YES | 5 | mg | DAILY | ORAL |

Listing 16 (2 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|-----------------------|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100114 | GEL | Male | 64 | LISINOPRIL | CARDIOVASCULAR SYSTEM | 2MAY2012 | YES | 5 | mg | DAILY | ORAL |
| . | . | . | . | LISINOPRIL | ARTERIAL HYPERTENSION | | | | | | |
| 100118 | DROP | Female | 78 | RATACAND | CARDIOVASCULAR SYSTEM | 6OCT2007 | YES | 16 | mg | DAILY | ORAL |
| . | . | . | . | CANDESARTAN | ARTERIAL HYPERTENSION | | | | | | |
| . | . | . | . | MEDIPO | CARDIOVASCULAR SYSTEM | 23JAN2001 | YES | 20 | mg | DAILY | ORAL |
| . | . | . | . | SIMVASTATIN | HYPERCHOLESTEROLEMIA | | | | | | |
| 100119 | DROP | Female | 72 | BLOPRESS | CARDIOVASCULAR SYSTEM | 2002 | YES | 16 | mg | DAILY | ORAL |
| . | . | . | . | CANDESARTAN | ARTERIAL HYPERTENSION | | | | | | |
| 100120 | GEL | Male | 79 | LISINOPRIL | CARDIOVASCULAR SYSTEM | 6MAY2005 | YES | mg | 5 | DAILY | ORAL |
| . | . | . | . | LISINOPRIL | ARTERIAL HYPERTENSION | | | | | | |
| 100121 | GEL | Male | 80 | LISINOPRIL | CARDIOVASCULAR SYSTEM | 2000 | YES | 20 | mg | DAILY | ORAL |
| . | . | . | . | LISINOPRIL | ARTERIAL HYPERTENSION | | | | | | |
| 100124 | GEL | Female | 71 | NEBILOX | CARDIOVASCULAR SYSTEM | FEB2001 | YES | 5 | MG | DAILY | ORAL |
| . | . | . | . | NEBIVOLOL | ARTERIAL HYPERTENSION | | | | | | |

Listing 16 (3 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|--|-----------------------|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100126 | GEL | Female | 85 | NELOTAN | CARDIOVASCULAR SYSTEM | 2005 | YES | 50 | mg | DAILY | ORAL |
| . | . | . | . | LOSARTAN | | | | | | | |
| . | . | . | . | ARTERIAL HYPERTENSION | | | | | | | |
| . | . | . | . | CRESTOR | CARDIOVASCULAR SYSTEM | 2008 | YES | 20 | mg | DAILY | ORAL |
| . | . | . | . | ROSUVASTATIN | | | | | | | |
| . | . | . | . | HYPERCHOLESTEROLEMIA | | | | | | | |
| 100128 | DROP | Male | 80 | CONGESCOR | CARDIOVASCULAR SYSTEM | APR2001 | YES | 1.25 | MG | DAILY | ORAL |
| . | . | . | . | BISOPROLOL | | | | | | | |
| . | . | . | . | ARTERIAL HYPERTENSION | | | | | | | |
| 100130 | GEL | Male | 66 | NORVASC | CARDIOVASCULAR SYSTEM | 2000 | YES | 5 | mg | DAILY | ORAL |
| . | . | . | . | AMLODIPINE | | | | | | | |
| . | . | . | . | ARTERIAL HYPERTENSION | | | | | | | |
| . | . | . | . | DILATREND | CARDIOVASCULAR SYSTEM | 2000 | YES | 12.5 | MG | DAILY | ORAL |
| . | . | . | . | CARVEDILOL | | | | | | | |
| . | . | . | . | ARTERIAL HYPERTENSION | | | | | | | |
| 100131 | DROP | Female | 77 | LOBIDIUR (NEBIVOLOLO+IDROCLOROTIAZIDE) | CARDIOVASCULAR SYSTEM | FEB2010 | YES | 5 | mg | DAILY | ORAL |
| . | . | . | . | NEBICARD-H | | | | | | | |
| . | . | . | . | ARTERIAL HYPERTENSION | | | | | | | |
| . | . | . | . | VALSARTAN | CARDIOVASCULAR SYSTEM | FEB2010 | YES | 40 | mg | DAILY | ORAL |
| . | . | . | . | VALSARTAN | | | | | | | |
| . | . | . | . | ARTERIAL HYPERTENSION | | | | | | | |

Listing 16 (4 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|---|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100133 | GEL | Male | 74 | ADALAT CRONO | CARDIOVASCULAR SYSTEM | MAR2005 | YES | 20 | mg | DAILY | ORAL |
| . | . | . | . | NIFEDIPINE | | | | | | | |
| . | . | . | . | ARTERIAL HYPERTENSION | | | | | | | |
| 100145 | GEL | Male | 81 | TOTALIP | CARDIOVASCULAR SYSTEM | 2003 | YES | 20 | mg | DAILY | ORAL |
| . | . | . | . | ATORVASTATIN | | | | | | | |
| . | . | . | . | HYPERCHOLESTEROLEMIA | | | | | | | |
| . | . | . | . | TRIATEC | CARDIOVASCULAR SYSTEM | 2003 | YES | 2.5 | mg | DAILY | ORAL |
| . | . | . | . | RAMIPRIL | | | | | | | |
| . | . | . | . | ARTERIAL HYPERTENSION | | | | | | | |
| 100149 | DROP | Female | 71 | EUTIROX | SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONE | 1995 | YES | 50 | mcg | DAILY | ORAL |
| . | . | . | . | LEVOTHYROXINE | | | | | | | |
| . | . | . | . | HYPOTHYROIDISM | | | | | | | |
| 100153 | DROP | Female | 81 | CONGESCOR | CARDIOVASCULAR SYSTEM | 2003 | YES | 1.25 | mg | DAILY | ORAL |
| . | . | . | . | BISOPROLOL | | | | | | | |
| . | . | . | . | ARTERIAL HYPERTENSION | | | | | | | |
| . | . | . | . | NORVASC | CARDIOVASCULAR SYSTEM | 2003 | YES | 5 | mg | ONCE | ORAL |
| . | . | . | . | AMLODIPINE | | | | | | | |
| . | . | . | . | ARTERIAL HYPERTENSION | | | | | | | |
| . | . | . | . | EUTIROX | SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONE | 2010 | YES | 100 | mg | DAILY | ORAL |
| . | . | . | . | LEVOTHYROXINE | | | | | | | |
| . | . | . | . | HYPERTHYROIDISM | | | | | | | |

Listing 16 (5 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|------------------------------------|-------------------------------------|--------------------------------|-------------------------|---------|---------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100154 | GEL | Female 68 | TRIATEC | . | CARDIOVASCULAR SYSTEM | FEB2007 | YES | 5 | mg | ONCE | ORAL |
| . | . | . | RAMIPRIL | . | ARTERIAL HYPERTENSION | | | | | | |
| 100155 | DROP | Female 79 | MILARDIS | . | CARDIOVASCULAR SYSTEM | 2002 | YES | 40 | mg | ONCE | ORAL |
| . | . | . | TELMISARTAN | . | ARTERIAL HYPERTENSION | | | | | | |
| 100201 | GEL | Female 80 | DELAPRIL 30 MG + INDAPAMIDE 2.5 MG | . | CARDIOVASCULAR SYSTEM | 2007 | YES | 15+1.25 | MG | DAILY | ORAL |
| . | . | . | DELAPRIDE | . | SYSTEMIC ARTERIAL HYPERTENSION | | | | | | |

Listing 16 (6 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|--|-------------------------------------|---|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100203 | DROP | Female 76 | PLAUNAZIDE 40+25 MG CARDIOVASCULAR SYSTEM BENICAR HCT SYSTEMIC ARTERIAL HYPERTENSION | . | . | 2007 | YES | 1 | cp | DAILY | ORAL |
| . | . | . | ALLOPURINOL 10 MG MUSCULO-SKELETAL SYSTEM ALLOPURINOL HYPERURICEMIA | . | . | 2007 | YES | 1 | cp | DAILY | ORAL |
| . | . | . | OMISTAT 10 MG CARDIOVASCULAR SYSTEM SIMVASTATIN HYPERCHOLESTEROLEMIA | . | . | 2007 | YES | 1 | cp | DAILY | ORAL |
| . | . | . | LANSOPRAZOLE 30 MG ALIMENTARY TRACT AND METABOLISM LANSOPRAZOLE GASTROESOPHAGEAL REFLUX | . | . | 2012 | YES | 1 | cp | DAILY | ORAL |
| . | . | . | TAVOR NERVOUS SYSTEM LORAZEPAM INSOMNIA | . | . | 2007 | YES | 1 | cp | DAILY | ORAL |
| 100204 | GEL | Male 71 | LOSARTAN 100 MG CARDIOVASCULAR SYSTEM LOSARTAN SYSTEMIC ARTERIAL HYPERTENSION | . | . | 2012 | YES | 1 | cp | DAILY | ORAL |
| . | . | . | PRADAXA 75 MG BLOOD AND BLOOD FORMING ORGANS DABIGATRAN ATRIAL FIBRILLATION | . | . | 2012 | YES | 1 | cp | DAILY | ORAL |
| . | . | . | NORMOPRESS 100+2.5 MG CARDIOVASCULAR SYSTEM METHYLDOPA SYSTEMIC ARTERIAL HYPERTENSION | . | . | 2012 | YES | 1 | cp | DAILY | ORAL |

Listing 16 (7 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|--|--|-------------------------|---------|------|-------|---------------|--------|
| | | | | Sex | | | | | | | |
| 100205 | GEL | Male | 75 | LACIREX 4 MG CARDIOVASCULAR SYSTEM | | 2011 | YES | 1 | cp | DAILY | ORAL |
| . | . | . | . | LACIDIPINE SYSTEMIC ARTERIAL HYPERTENSION | | | | | | | |
| . | . | . | . | LOBIVON 5 MG CARDIOVASCULAR SYSTEM | | 2011 | YES | 1/4 | cp | DAILY | ORAL |
| . | . | . | . | NEBIVOLOL SYSTEMIC ARTERIAL HYPERTENSION | | | | | | | |
| . | . | . | . | LUCEN 20 MG ALIMENTARY TRACT AND METABOLISM | | 2007 | YES | 1 | cp | DAILY | ORAL |
| . | . | . | . | ESOMEPRAZOLE GASTROESOPHAGEAL REFLUX | | | | | | | |
| 100206 | DROP | Female | 81 | SIMVASTATINA 20 MG CARDIOVASCULAR SYSTEM | | 2008 | YES | 1 | cp | DAILY | ORAL |
| . | . | . | . | SIMVASTATIN HYPERCHOLESTEROLEMIA | | | | | | | |
| . | . | . | . | LUCEN 20 MG ALIMENTARY TRACT AND METABOLISM | | 2013 | YES | 1 | cp | DAILY | ORAL |
| . | . | . | . | ESOMEPRAZOLE GASTROESOPHAGEAL REFLUX | | | | | | | |
| . | . | . | . | SYSTANE IDRA SENSORY ORGANS | | 2016 | YES | 1 | drop | TWICE PER DAY | OCULAR |
| . | . | . | . | SYSTANE LUBRICANT DRY EYE SYNDROME | | | | | | | |

Listing 16 (8 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|---|-------------------------------------|---|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100207 | DROP | Female 65 | TAREG 40 MG CARDIOVASCULAR SYSTEM VALSARTAN SYSTEMIC ARTERIAL HYPERTENSION | . | . | 2013 | YES | 1 | cp | DAILY | ORAL |
| | | | EZIMEGA PLUS | . | . | 2008 | YES | 1 | cp | DAILY | ORAL |
| | | | HYPERCHOLESTEROLEMIA | . | . | | | | | | |
| 100208 | GEL | Female 79 | PAROXETINA 20 MG NERVOUS SYSTEM PAROXETINE DEPRESSION | . | . | 2015 | YES | 1 | drop | DAILY | ORAL |
| | | | | . | . | | | | | | |
| 100209 | GEL | Female 77 | TAVOR 1 MG NERVOUS SYSTEM LORAZEPAM INSOMNIA | . | . | 2008 | YES | 1 | cp | DAILY | ORAL |
| | | | SEQUACOR 2.5 MG CARDIOVASCULAR SYSTEM BISOPROLOL ARRHYTHMIA | . | . | 2008 | YES | 1 | cp | DAILY | ORAL |
| 100210 | DROP | Female 70 | SIMVASTATINA 20 MG CARDIOVASCULAR SYSTEM SIMVASTATIN HYPERCHOLESTEROLEMIA | . | . | 2012 | YES | 1 | cp | DAILY | ORAL |
| | | | | . | . | | | | | | |
| 100211 | GEL | Male 67 | OMISTAT 20 MG CARDIOVASCULAR SYSTEM SIMVASTATIN HYPERCHOLESTEROLEMIA | . | . | 2014 | YES | 1 | cp | DAILY | ORAL |
| | | | | . | . | | | | | | |

Listing 16 (9 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|---|-------------------------------------|---|-------------------------|---------|----------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100212 | DROP | Female 82 | OMEPRAZOLO DIGERENT 150 MG ALIMENTARY TRACT AND METABOLISM OMEPRAZOLE GASTROPHAGEAL REFLUX | . | . | 2016 | YES | 1 | cp | DAILY | ORAL |
| 100213 | DROP | Female 81 | EUTIROX 100 MCG SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONE LEVOTHYROXINE HYPOTHYROIDISM NEBIVOLOLO 5 MG CARDIOVASCULAR SYSTEM NEBIVOLOL SYSTEMIC ARTERIAL HYPERTENSION ASPIRINETTA BLOOD AND BLOOD FORMING ORGANS ACETYLSALICYLIC ACID CARDIOVASCULAR PROPHYLAXIS HYALISTIL SENSORY ORGANS HYALURONIC ACID DRY EYE SYNDROME | . | . | 1988 | YES | 1 | cp | DAILY | ORAL |
| 100214 | DROP | Female 77 | TORVAST CARDIOVASCULAR SYSTEM ATORVASTATIN HYPERCHOLESTEROLEMIA COTAREG CARDIOVASCULAR SYSTEM CO-DIOVAN SYSTEMIC ARTERIAL HYPERTENSION | . | . | 2010 | YES | 20 | mg | DAILY | ORAL |
| . | . | . | 1996 | . | . | | YES | 160+12,5 | mg | DAILY | ORAL |

Listing 16 (10 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--|-------------------------|---------|------|-------|-----------------|-------|
| | | | | Sex | | | | | | | |
| 100217 | DROP | Female 72 | NORMOPRESS 100+12.5 MG | . | CARDIOVASCULAR SYSTEM | 2008 | YES | 1 | tab | DAILY | ORAL |
| . | . | . | METHYLDOPA | . | SYSTEMIC ARTERIAL HYPERTENSION | | | | | | |
| 100219 | GEL | Female 83 | RAMIPRIL | . | CARDIOVASCULAR SYSTEM | 2013 | YES | 5 | MG | DAILY | ORAL |
| . | . | . | RAMIPRIL | . | SYSTEMIC ARTERIAL HYPERTENSION | | | | | | |
| 100220 | GEL | Male 64 | CELLCEPT | . | ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS | 2010 | YES | 500 | MG | 3 TIMES PER DAY | ORAL |
| . | . | . | MYCOPHENOLIC ACID | . | SCLERODERMA | | | | | | |
| . | . | . | REVATIO | . | CARDIOVASCULAR SYSTEM | 2015 | YES | 20 | MG | DAILY | ORAL |
| . | . | . | SILDENAFIL | . | PULMONARY HYPERTENSION | | | | | | |
| . | . | . | TRACLEER | . | CARDIOVASCULAR SYSTEM | 2015 | YES | 125 | MG | TWICE PER DAY | ORAL |
| . | . | . | BOSENTAN | . | PULMONARY HYPERTENSION | | | | | | |
| . | . | . | BISOPROLOLO | . | CARDIOVASCULAR SYSTEM | 2014 | YES | 1,2 | MG | DAILY | ORAL |
| . | . | . | BISOPROLOL | . | SYSTEMIC ARTERIAL HYPERTENSION | | | | | | |
| 100221 | GEL | Female 76 | ALAPRIL | . | CARDIOVASCULAR SYSTEM | 2008 | YES | 20 | MG | DAILY | ORAL |
| . | . | . | LISINOPRIL | . | SYSTEMIC ARTERIAL HYPERTENSION | | | | | | |

Listing 16 (11 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--------------------------------|-------------------------|---------|------|-------|-----------|-------|
| | | | | Sex | | | | | | | |
| 100222 | DROP | Female | 76 | VALSARTAN | CARDIOVASCULAR SYSTEM | 2008 | YES | 160 | MG | DAILY | ORAL |
| . | . | . | . | VALSARTAN | | | | | | | |
| . | . | . | . | SYSTEMIC ARTERIAL HYPERTENSION | | | | | | | |
| . | . | . | . | BISOPROLOLO | CARDIOVASCULAR SYSTEM | 2008 | YES | 1.25 | MG | DAILY | ORAL |
| . | . | . | . | BISOPROLOL | | | | | | | |
| . | . | . | . | SYSTEMIC ARTERIAL HYPERTENSION | | | | | | | |
| . | . | . | . | LASIX | CARDIOVASCULAR SYSTEM | 2008 | YES | 25 | MG | AS NEEDED | ORAL |
| . | . | . | . | FUROSEMIDE | | | | | | | |
| . | . | . | . | SYSTEMIC ARTERIAL HYPERTENSION | | | | | | | |
| 100223 | DROP | Male | 61 | CARDIOASPIRIN | BLOOD AND BLOOD FORMING ORGANS | 2015 | YES | 100 | MG | DAILY | ORAL |
| . | . | . | . | BLOOD AND BLOOD FORMING ORGANS | | | | | | | |
| . | . | . | . | ACETYLSALICYLIC ACID | | | | | | | |
| . | . | . | . | ISCHEMIC STROKE | | | | | | | |

Listing 16 (12 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|---|-------------------------------------|------|-------------------------|---------|------|--------|-------|-------|
| | | | | Code | Drug | | | | | | |
| 100224 | GEL | Female 75 | KARVEZIDE 300+25 MG CARDIOVASCULAR SYSTEM KARVEA HCT SYSTEMIC ARTERIAL HYPERTENSION | | | 2005 | YES | 1 | tablet | DAILY | ORAL |
| . | . | . | FULCROSUPRA CARDIOVASCULAR SYSTEM FENOFIBRATE HYPERLIPIDEMIA | | | 2013 | YES | 145 | mg | DAILY | ORAL |
| . | . | . | XANAX NERVOUS SYSTEM ALPRAZOLAM ANXIETY | | | 2015 | YES | 0,5 | mg | DAILY | ORAL |
| . | . | . | CARDIOASPIRINA BLOOD AND BLOOD FORMING ORGANS ACETYLSALICYLIC ACID CARDIOVASCULAR PROPHYLAXIS | | | 2013 | YES | 100 | mg | DAILY | ORAL |
| . | . | . | OMEPRAZEN ALIMENTARY TRACT AND METABOLISM OMEPRAZOLE GASTRIC PROTECTION | | | 2013 | YES | 10 | mg | DAILY | ORAL |
| 100225 | DROP | Female 79 | TRIATEC 2.5 MG CARDIOVASCULAR SYSTEM RAMIPRIL SYSTEMIC HYPERTENSION | | | 2008 | YES | 1 | tablet | DAILY | ORAL |
| . | . | . | CARDIOASPIRIN 100 MG BLOOD AND BLOOD FORMING ORGANS ACETYLSALICYLIC ACID CARDIOVASCULAR PREVENTION | | | 2013 | YES | 1 | tablet | DAILY | ORAL |

Listing 16 (13 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|--|-------------------------------------|---------|-------------------------|---------|------|--------|-------|-------|
| | | | | Start date/ End date | Ongoing | | | | | | |
| 100226 | GEL | Female 74 | COMBISARTAN 160+12.5 CARDIOVASCULAR SYSTEM CO-DIOVAN SYSTEMIC HYPERTENSION | | | 2008 | YES | 1 | tablet | DAILY | ORAL |
| . | . | . | LOBIVON 5 MG CARDIOVASCULAR SYSTEM NEBIVOLOL SYSTEMIC HYPERTENSION | | | 2008 | YES | 1 | tablet | DAILY | ORAL |
| . | . | . | SAMYR 400 MG NERVOUS SYSTEM ADEMETIONINE DEPRESSION | | | 2010 | YES | 1 | tablet | DAILY | ORAL |
| 100227 | DROP | Female 68 | OLPRESS 20 MG CARDIOVASCULAR SYSTEM OLMESARTAN SYSTEMIC HYPERTENSION | | | 2009 | YES | 1 | tablet | DAILY | ORAL |
| . | . | . | SIMVASTATINA 20 MG CARDIOVASCULAR SYSTEM SIMVASTATIN HYPERCHOLESTEROLEMIA | | | 2012 | YES | 1 | tablet | DAILY | ORAL |
| . | . | . | PLAVIX 75 MG BLOOD AND BLOOD FORMING ORGANS CLOPIDOGREL CARDIOVASCULAR PREVENTION | | | 2016 | YES | 1 | tablet | DAILY | ORAL |

Listing 16 (14 of 64): Concomitant treatments

Listing 16 (15 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Sex | Preferred term/ Indication | Reported term/ Therapeutic area/ | | | | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-----|---|-------------------------------------|--|--|--|--|-------------------------|---------|------|--------|-------|-------|
| | | | | | | | | | | | | | | | |
| 100231 | DROP | Female | 74 | SELES BETA 100 MG CARDIOVASCULAR SYSTEM ATENOLOL SYSTEMIC HYPERTENSION | | | | | | 2011 | YES | 1 | tablet | DAILY | ORAL |
| . | . | . | . | LEXOTAN 2.5 MG/ML NERVOUS SYSTEM BROMAZEPAM ANXIETY | | | | | | 2016 | YES | 15 | gtt | DAILY | ORAL |
| . | . | . | . | PEPTAZOL 20 MG ALIMENTARY TRACT AND METABOLISM LANSOPRAZOLE MRGE | | | | | | 2013 | YES | 1 | tablet | DAILY | ORAL |
| 100232 | DROP | Female | 73 | LOBIVON 5 MG CARDIOVASCULAR SYSTEM NEBIVOLOL SYSTEMIC HYPERTENSION | | | | | | 2010 | YES | 1 | tablet | DAILY | ORAL |

Listing 16 (16 of 64): Concomitant treatments

Listing 16 (17 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Reported term/ Therapeutic area/ Preferred term/ Indication | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|----------------------|---------------|---|-------------------------|---------|------|--------|---------------|-------|
| 100234 | GEL | Female 73 | PRADAXA BLOOD AND BLOOD FORMING ORGANS DABIGATRAN ATRIAL FIBRILLATION | 2013 | YES | 150 | mg | TWICE PER DAY | ORAL |
| . | . | . | CORDARONE CARDIOVASCULAR SYSTEM AMIODARONE ATRIAL FIBRILLATION | 2013 | YES | 50 | mg | DAILY | ORAL |
| . | . | . | GIANT 20MG +5MG CARDIOVASCULAR SYSTEM OLMESAFA AM SYSTEMIC ARTERIAL HYPERTENSION | 2010 | YES | 1 | tablet | DAILY | ORAL |
| . | . | . | EUTIROX SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONE LEVOTHYROXINE HYPOTHYROIDISM | 2013 | YES | 75 | mcg | DAILY | ORAL |
| . | . | . | ATORVASTATINA CARDIOVASCULAR SYSTEM ATORVASTATIN HYPERCHOLESTEROLEMIA | 2013 | YES | 20 | mg | DAILY | ORAL |
| 100236 | DROP SUBCUTANEOUS | Female 70 | TERIPARATIDE SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONE TERIPARATIDE OSTEOPOROSIS | 2017 | YES | 20 | mg | DAILY | |

Listing 16 (18 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|---------------------------------|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100237 | DROP | Male | 73 | CARDIOASPIRIN | BLOOD AND BLOOD FORMING ORGANS | 2015 | YES | 100 | mg | DAILY | ORAL |
| . | . | . | . | ACETYLSALICYLIC ACID | | | | | | | |
| . | . | . | . | PRIMARY CARDIOVASCULAR PROPHYLAXIS | | | | | | | |
| . | . | . | . | PRISMA | BLOOD AND BLOOD FORMING ORGANS | 2015 | YES | 50 | mg | DAILY | ORAL |
| . | . | . | . | MESOGLYCAN | | | | | | | |
| . | . | . | . | PRIMARY CARDIOVASCULAR PROPHYLAXIS | | | | | | | |
| 100238 | GEL | Male | 78 | DROMOS | ALIMENTARY TRACT AND METABOLISM | 2015 | YES | 500 | mg | DAILY | ORAL |
| . | . | . | . | LEVOCARNITINE | | | | | | | |
| . | . | . | . | CHRONIC HEART FAILURE | | | | | | | |
| 100239 | DROP | Female | 80 | LIXIANA | BLOOD AND BLOOD FORMING ORGANS | 2014 | YES | 60 | mg | DAILY | ORAL |
| . | . | . | . | EDOXABAN | | | | | | | |
| . | . | . | . | ATRIAL FIBRILLATION | | | | | | | |
| . | . | . | . | ATENOLOLO | CARDIOVASCULAR SYSTEM | 2014 | YES | 50 | mg | DAILY | ORAL |
| . | . | . | . | ATENOLOL | | | | | | | |
| . | . | . | . | ATRIAL FIBRILLATION | | | | | | | |

Listing 16 (19 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|---|-------------------------------------|--|-------------------------|---------|------|--------|---------------|------------|
| | | | | Sex | | | | | | | |
| 100240 | | Female 72 | CRESTOR 5 MG CARDIOVASCULAR SYSTEM ROSUVASTATIN HYPERCHOLESTEROLEMIA | | | 2008 | YES | 1 | tablet | DAILY | ORAL |
| | | . | ZYLLT 75 MG BLOOD AND BLOOD FORMING ORGANS CLOPIDOGREL ISCHEMIC CARDIOMYOPATHY | . | | 2012 | YES | 1 | tablet | DAILY | ORAL |
| | | . | CONGESCOR 3.75 MG CARDIOVASCULAR SYSTEM BISOPROLOL ISCHEMIC CARDIOMYOPATHY | . | | 2012 | YES | 1 | tablet | DAILY | ORAL |
| | | . | FOSTER 100 MCG + 6 MCG RESPIRATORY SYSTEM BEKFORM ASTHMA | . | | 2013 | YES | 1 | puff | DAILY | INHALATION |
| 100241 GEL | | Female 74 | ALENDROS MUSCULO-SKELETAL SYSTEM ALENDRONIC ACID OSTEOPOROSIS | | | 1998 | YES | 70 | mg | DAILY | ORAL |
| | | . | NATECAL D3 600 MG +400UI ALIMENTARY TRACT AND METABOLISM CALCIUM OSTEOPOROSIS | . | | 1998 | YES | 1 | tablet | TWICE PER DAY | ORAL |
| | | . | TOTALIP CARDIOVASCULAR SYSTEM ATORVASTATIN HYPERCHOLESTEROLEMIA | . | | 1998 | YES | 10 | mg | DAILY | ORAL |

Listing 16 (20 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|---|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100243 | DROP | Male | 74 | PLAVIX | BLOOD AND BLOOD FORMING ORGANS | 2015 | YES | 75 | mg | DAILY | ORAL |
| . | . | . | . | CLOPIDOGREL | | | | | | | |
| . | . | . | . | ISCHEMIC CARDIOPATHY | | | | | | | |
| . | . | . | . | ALTIAZEM | CARDIOVASCULAR SYSTEM | 2015 | YES | 60 | mg | DAILY | ORAL |
| . | . | . | . | DILTIAZEM | | | | | | | |
| . | . | . | . | ISCHEMIC CARDIOPATHY | | | | | | | |
| . | . | . | . | MONOCINQUE | CARDIOVASCULAR SYSTEM | 2015 | YES | 20 | mg | DAILY | ORAL |
| . | . | . | . | ISOSORBIDE | | | | | | | |
| . | . | . | . | ISCHEMIC CARDIOPATHY | | | | | | | |
| . | . | . | . | TRIATEC | CARDIOVASCULAR SYSTEM | 2008 | YES | 2.5 | mg | DAILY | ORAL |
| . | . | . | . | RAMIPRIL | | | | | | | |
| . | . | . | . | SYSTEMIC ARTERIAL HYPERTENSION | | | | | | | |
| . | . | . | . | TOTALIP | CARDIOVASCULAR SYSTEM | 2015 | YES | 20 | mg | DAILY | ORAL |
| . | . | . | . | ATORVASTATIN | | | | | | | |
| . | . | . | . | HYPERCHOLESTEROLEMIA | | | | | | | |
| . | . | . | . | PLAQUENIL | ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLEN | 2013 | YES | 200 | mg | DAILY | ORAL |
| . | . | . | . | HYDROXYCHLOROQUINE | | | | | | | |
| . | . | . | . | PSORIATIC ARTHRITIS | | | | | | | |

Listing 16 (21 of 64): Concomitant treatments

| Sbj | Study | Age | Preferred term/ Therapeutic area/ | Start date/ | End date | Ongoing | Dose | Units | Freq. | Route |
|--------|-------|--------|--------------------------------------|---------------------------------|----------|----------|------|-------|-------|-------|
| Code | drug | Sex | (year) | Indication | | | | | | |
| 100244 | GEL | Female | 66 | ARIXTRA SUBCUTANEOUS | | OCT 2018 | YES | 2.5 | mg | ONCE |
| . | . | . | . | BLOOD AND BLOOD FORMING ORGANS | | | | | | |
| . | . | . | . | FONDAPARINUX | | | | | | |
| . | . | . | . | SUPERFICIAL THROMBOPHLEBITIS | | | | | | |
| . | . | . | . | SOTALOL | 2016 | YES | 80 | mg | ONCE | ORAL |
| . | . | . | . | CARDIOVASCULAR SYSTEM | | | | | | |
| . | . | . | . | SOTALOL | | | | | | |
| . | . | . | . | EXTRASYSTOLIA | | | | | | |
| . | . | . | . | ESCITALOPRAM | 2015 | YES | 10 | mg | ONCE | ORAL |
| . | . | . | . | NERVOUS SYSTEM | | | | | | |
| . | . | . | . | ESCITALOPRAM | | | | | | |
| . | . | . | . | ANXIOUS SYNDROME | | | | | | |
| 100245 | DROP | Female | 69 | ALLOPURINOL | 2016 | YES | 300 | MG | DAILY | ORAL |
| . | . | . | . | MUSCULO-SKELETAL SYSTEM | | | | | | |
| . | . | . | . | ALLOPURINOL | | | | | | |
| . | . | . | . | HYPURICEMIA | | | | | | |
| . | . | . | . | LASIX | 2017 | YES | 25 | MG | DAILY | ORAL |
| . | . | . | . | CARDIOVASCULAR SYSTEM | | | | | | |
| . | . | . | . | FUROSEMIDE | | | | | | |
| . | . | . | . | HYDRIC RETENTION | | | | | | |
| 100301 | GEL | Female | 68 | OROTRE | UNK | YES | 1 | 1 | DAILY | ORAL |
| . | . | . | . | ALIMENTARY TRACT AND METABOLISM | UNK | | | | | |
| . | . | . | . | LEKOVIT CA | | | | | | |
| . | . | . | . | BONE DESIASE | | | | | | |
| . | . | . | . | LEXOTAN | UNK | YES | 1 | 1 | DAILY | ORAL |
| . | . | . | . | NERVOUS SYSTEM | UNK | | | | | |
| . | . | . | . | BROMAZEPAM | | | | | | |
| . | . | . | . | ANXIUS SYNDROME | | | | | | |

Listing 16 (22 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100302 | GEL | Male | 61 | METFORAL | ALIMENTARY TRACT AND METABOLISM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | METFORMIN | | | | | | | |
| . | . | . | . | DIABETES | | | | | | | |
| . | . | . | . | SIMVASTATINA | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | SIMVASTATIN | | | | | | | |
| . | . | . | . | DISLIPIDEMY | | | | | | | |
| . | . | . | . | ATENOLOLO | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | ATENOLOL | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | CARDIOASA | BLOOD AND BLOOD FORMING ORGANS | UNK | YES | 100 | mg | DAILY | ORAL |
| . | . | . | . | ACETYLSALICYLIC ACID | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | CLOPIDOGREL | BLOOD AND BLOOD FORMING ORGANS | UNK | YES | 75 | mg | DAILY | ORAL |
| . | . | . | . | CLOPIDOGREL | | | | | | | |
| . | . | . | . | CARDIOVASCULAR DISEASE | | | | | | | |
| . | . | . | . | PRADIF | GENITO URINARY SYSTEM AND SEX HORMONES | UNK | YES | 400 | mg | DAILY | ORAL |
| . | . | . | . | TAMSULOSIN | | | | | | | |
| . | . | . | . | NEPHROPATHY | | | | | | | |
| 100303 | DROP | Female | 73 | ENALAPRIL | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | ENALAPRIL | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | LOBIDIVON | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | NEBIVOLOL | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |

Listing 16 (23 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|---|-------------------------|---------|------|-------|-------|-------|
| 100305 | DROP | Female 85 | EUTIROX | SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONE | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | LEVOTHYROXINE | | | | | | | |
| . | . | . | HYPOTIROIDISM | | | | | | | |
| . | . | . | MODURETIC | MODURETIC | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | CARDIOVASCULAR SYSTEM | CARDIOVASCULAR SYSTEM | | | | | | |
| . | . | . | MODURETIC | MODURETIC | | | | | | |
| . | . | . | HYPERTENSION | HYPERTENSION | | | | | | |
| . | . | . | RAMIPRIL | RAMIPRIL | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | CARDIOVASCULAR SYSTEM | CARDIOVASCULAR SYSTEM | | | | | | |
| . | . | . | RAMIPRIL | RAMIPRIL | | | | | | |
| . | . | . | HYPERTENSION | HYPERTENSION | | | | | | |
| 100306 | DROP | Female 84 | ACESISTEM | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | VASERETIC | VASERETIC | | | | | | |
| . | . | . | HYPERTENSION | HYPERTENSION | | | | | | |
| 100307 | GEL | Female 73 | EUTIROX | SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONE | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | LEVOTHYROXINE | LEVOTHYROXINE | | | | | | |
| . | . | . | HYPOTIROIDISM | HYPOTIROIDISM | | | | | | |
| 100308 | GEL | Female 85 | COMBISARTAN | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | mg | DAILY | ORAL |
| . | . | . | CO-DIOVAN | CO-DIOVAN | | | | | | |
| . | . | . | HYPERTENSION | HYPERTENSION | | | | | | |
| 100310 | GEL | Female 73 | ASPIRENNETTA | BLOOD AND BLOOD FORMING ORGANS | 2017 | YES | 100 | mg | DAILY | ORAL |
| . | . | . | ACETYLSALICYLIC ACID | ACETYLSALICYLIC ACID | | | | | | |
| . | . | . | SYSTEMIC THERAPY | SYSTEMIC THERAPY | | | | | | |

Listing 16 (24 of 64): Concomitant treatments

Listing 16 (25 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--|-------------------------|---------|------|-------|-----------------|------------|
| | | | | Sex | | | | | | | |
| 100313 | GEL | Male | 71 | DIAMOX CPR | SENSORY ORGANS | 4DEC2017 | YES | 250 | mg | ONCE | ORAL |
| . | . | . | . | ACETAZOLAMIDE | | | | | | | |
| . | . | . | . | BREAKAGE POSTERIORE CAPSULE | | | | | | | |
| . | . | . | . | VIGAMOX DROP | SENSORY ORGANS | 4DEC2017 | YES | 190 | mg | 3 TIMES PER DAY | OCULAR |
| . | . | . | . | MOXIFLOXACIN | | | | | | | |
| . | . | . | . | BREAKAGE POSTERIORE CAPSULE | | | | | | | |
| 100314 | DROP | Male | 67 | AVODART | GENITO URINARY SYSTEM AND SEX HORMONES | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | DUTASTERIDE | | | | | | | |
| . | . | . | . | PROSTATIC HYPERTROPHY | | | | | | | |
| 100315 | GEL | Female | 65 | DEPAKIN | NERVOUS SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | VALPROIC ACID | | | | | | | |
| . | . | . | . | ANXIUS SYNDROME | | | | | | | |
| . | . | . | . | XANAX | NERVOUS SYSTEM | UNK | YES | 1 | # | DAILY | SUBLINGUAL |
| . | . | . | . | ALPRAZOLAM | | | | | | | |
| . | . | . | . | ANXIUS SYNDROME | | | | | | | |

Listing 16 (26 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|--|---------|-------------------------|---------|------|-------|-------|-------|
| | | | | Start date/ End date | Ongoing | | | | | | |
| 100316 | DROP | Male | 76 | OMNIC | | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | | GENITO URINARY SYSTEM AND SEX HORMONES | | | | | | | |
| . | . | . | | TAMSULOSIN | | | | | | | |
| . | . | . | | PROSTATIC HYPERTROPHY | | | | | | | |
| . | . | . | | PROSTANOX | | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | | VARIOUS | | | | | | | |
| . | . | . | | SERENOA REPENS | | | | | | | |
| . | . | . | | PROSTATIC HYPERTROPHY | | | | | | | |
| . | . | . | | PROSTIDE | | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | | GENITO URINARY SYSTEM AND SEX HORMONES | | | | | | | |
| . | . | . | | FINASTERIDE | | | | | | | |
| . | . | . | | PROSTATIC HYPERTROPHY | | | | | | | |
| 100317 | GEL | Male | 85 | AVODART | | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | | GENITO URINARY SYSTEM AND SEX HORMONES | | | | | | | |
| . | . | . | | DUTASTERIDE | | | | | | | |
| . | . | . | | PROSTATIC HYPERTROPHY | | | | | | | |
| . | . | . | | CARDIOASPIRINA | | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | | BLOOD AND BLOOD FORMING ORGANS | | | | | | | |
| . | . | . | | ACETYLSALICYLIC ACID | | | | | | | |
| . | . | . | | HYPERTENSION | | | | | | | |
| . | . | . | | HAMODEP | | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | | | | | | | | | |
| . | . | . | | PROSTATIC HYPERTROPHY | | | | | | | |
| . | . | . | | XATRAL | | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | | GENITO URINARY SYSTEM AND SEX HORMONES | | | | | | | |
| . | . | . | | ALFUZOSIN | | | | | | | |
| . | . | . | | PROSTATIC HYPERTROPHY | | | | | | | |

Listing 16 (27 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|---|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100318 | GEL | Female | 80 | RAMIPRIL | CARDIOVASCULAR SYSTEM | UNK | YES | 500 | mg | DAILY | ORAL |
| . | . | . | . | RAMIPRIL | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | CARDIOASPRINA | BLOOD AND BLOOD FORMING ORGANS | UNK | YES | 100 | mg | ONCE | ORAL |
| . | . | . | . | ACETYLSALICYLIC ACID | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| 100320 | DROP | Male | 69 | BISOPROLOLO | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | BISOPROLOL | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | CARDIOASPIRINA | BLOOD AND BLOOD FORMING ORGANS | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | ACETYLSALICYLIC ACID | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | PANTOPRAZOLE | ALIMENTARY TRACT AND METABOLISM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | PANTOPRAZOLE | | | | | | | |
| . | . | . | . | GASTRIC PROTECTOR | | | | | | | |
| 100321 | GEL | Male | 72 | ATENOLOLO | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | ATENOLOL | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | EUTIROX | SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONE | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | LEVOTHYROXINE | | | | | | | |
| . | . | . | . | HYPOTHYROIDISM | | | | | | | |

Listing 16 (28 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--------------------------------|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100322 | GEL | Male | 80 | TRIATEC | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | RAMIPRIL | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | CARDIOASPIRINA | BLOOD AND BLOOD FORMING ORGANS | | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | ACETYLSALICYLIC ACID | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| 100323 | DROP | Female | 76 | SINVASTATINA | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | SIMVASTATIN | | | | | | | |
| . | . | . | . | HYPERCOLESTEROLEMIA | | | | | | | |
| . | . | . | . | FASAVANCE | MUSCULO-SKELETAL SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | FOSAVANCE | | | | | | | |
| . | . | . | . | BONE DESEASE | | | | | | | |
| 100325 | GEL | Female | 83 | CARVEDILOLO | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | CARVEDIOL | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |

Listing 16 (29 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|---------------------------------|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100326 | DROP | Male | 81 | NEBIVOLOLO | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | NEBIVOLOL | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | COUMADIN | BLOOD AND BLOOD FORMING ORGANS | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | WARFARIN | | | | | | | |
| . | . | . | . | ANGIOPATHY | | | | | | | |
| . | . | . | . | KANRENOOL | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | CANRENOIC ACID | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | IGROTAN | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | CHLORTALIDONE | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| 100327 | GEL | Female | 73 | BONVIVA | MUSCULO-SKELETAL SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | IBANDRONIC ACID | | | | | | | |
| . | . | . | . | OSTEOPOROSIS | | | | | | | |
| . | . | . | . | DIBASE | ALIMENTARY TRACT AND METABOLISM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | COLECALCIFEROL | | | | | | | |
| . | . | . | . | OSTEOPOROSIS | | | | | | | |

Listing 16 (30 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--------------------------------|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100328 | DROP | Male | 82 | CARDIRENE | BLOOD AND BLOOD FORMING ORGANS | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | ACETYLSALICYLIC ACID | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | SELOKEN | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | METOPROLOL | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | PROVISACOR | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | ROSUVASTATIN | | | | | | | |
| . | . | . | . | HYPERCOLESTEROLEMIA | | | | | | | |
| 100329 | GEL | Male | 74 | CARDIOASPIRINA | BLOOD AND BLOOD FORMING ORGANS | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | ACETYLSALICYLIC ACID | | | | | | | |
| . | . | . | . | VASCULOPHATY-HIPERTENSION | | | | | | | |
| 100330 | DROP | Male | 61 | ASA | BLOOD AND BLOOD FORMING ORGANS | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | ACETYLSALICYLIC ACID | | | | | | | |
| . | . | . | . | CARDIOPHATHY | | | | | | | |
| . | . | . | . | BISOPROLOLO | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | BISOPROLOL | | | | | | | |
| . | . | . | . | CARDIOPHATHY | | | | | | | |
| . | . | . | . | CLOPIDOGREL | BLOOD AND BLOOD FORMING ORGANS | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | CLOPIDOGREL | | | | | | | |
| . | . | . | . | CARDIOPHATHY | | | | | | | |

Listing 16 (31 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--------------------------------|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100331 | GEL | Female | 71 | STATINA | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | SIMVASTATIN | | | | | | | |
| . | . | . | . | CARDIOPATHY | | | | | | | |
| 100332 | DROP | Male | 82 | KARVEZIDE | CARDIOVASCULAR SYSTEM | UNK | YES | 150 | mg | DAILY | ORAL |
| . | . | . | . | KARVEA HCT | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | ATORVASTINA | CARDIOVASCULAR SYSTEM | UNK | YES | 20 | mg | DAILY | ORAL |
| . | . | . | . | ATORVASTATIN | | | | | | | |
| . | . | . | . | VASCULOPATHY | | | | | | | |
| . | . | . | . | CARDIOASPIRINA | BLOOD AND BLOOD FORMING ORGANS | UNK | YES | 100 | mg | DAILY | ORAL |
| . | . | . | . | ACETYLSALICYLIC ACID | | | | | | | |
| . | . | . | . | VASCULOPATHY | | | | | | | |
| . | . | . | . | LERCANIDIPINA | CARDIOVASCULAR SYSTEM | UNK | YES | 10 | mg | DAILY | ORAL |
| . | . | . | . | LERCANIDIPINE | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | METOPROLOLO | CARDIOVASCULAR SYSTEM | UNK | YES | 100 | mg | DAILY | ORAL |
| . | . | . | . | METOPROLOL | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| 100333 | DROP | Male | 62 | LENDORMIN | NERVOUS SYSTEM | UNK | YES | 0.25 | mg | DAILY | ORAL |
| . | . | . | . | BROTIZOLAM | | | | | | | |
| . | . | . | . | INSOMNIA | | | | | | | |

Listing 16 (32 of 64): Concomitant treatments

| Sbj | Study | Age | Preferred term/ Therapeutic area/ | Start date/ | End date | Ongoing | Dose | Units | Freq. | Route |
|--------|-------|--------|--------------------------------------|--|----------|---------|------|-------|-------|-------|
| Code | drug | Sex | (year) | Indication | | | | | | |
| 100334 | GEL | Male | 72 | ASA BLOOD AND BLOOD FORMING ORGANS ACETYLSALICYLIC ACID HYPERTENSION | UNK | YES | 1 | # | ONCE | ORAL |
| . | . | . | . | SOTALEX CARDIOVASCULAR SYSTEM SOTALOL HYPERTENSION | UNK | YES | 80 | # | ONCE | ORAL |
| 100335 | DROP | Female | 80 | APROVEL CARDIOVASCULAR SYSTEM IRBESARTAN HYPERTENSION | UNK | YES | 150 | mg | DAILY | ORAL |
| . | . | . | . | ESAMEPRAZOLO ALIMENTARY TRACT AND METABOLISM ESOMEPRAZOLE GASTRIC PROTECTOR | UNK | YES | # | # | ONCE | ORAL |
| 100336 | GEL | Female | 82 | MODURETIC CARDIOVASCULAR SYSTEM MODURETIC HYPERTENSION | UNK | YES | 1 | # | ONCE | ORAL |
| 100340 | DROP | Male | 83 | COMBISARTAN CARDIOVASCULAR SYSTEM CO-DIOVAN HYPERTENSION | UNK | YES | 1 | # | DAILY | ORAL |

Listing 16 (33 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--------------------------------|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100341 | GEL | Male | 88 | AMLODIPINA | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | AMLODIPINE | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | CARDIOASA | BLOOD AND BLOOD FORMING ORGANS | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | ACETYLSALICYLIC ACID | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| 100342 | DROP | Female | 86 | BISOPROLOLO | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | BISOPROLOL | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | CARDIOASA | BLOOD AND BLOOD FORMING ORGANS | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | ACETYLSALICYLIC ACID | | | | | | | |
| . | . | . | . | HYPERTESION | | | | | | | |
| 100343 | GEL | Male | 74 | KARVEA | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | IRBESARTAN | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | SINVASTATINA | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | SIMVASTATIN | | | | | | | |
| . | . | . | . | HYPERCOLESTEROLEMY | | | | | | | |

Listing 16 (34 of 64): Concomitant treatments

| Sbj | Study | Age | Preferred term/ Therapeutic area/ | Start date/ | End date | Ongoing | Dose | Units | Freq. | Route |
|--------|-------|--------|--------------------------------------|---|----------|---------|------|-------|-------|-------|
| Code | drug | Sex | (year) | Indication | | | | | | |
| 100346 | DROP | Female | 77 | CARDIOASA | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | BLOOD AND BLOOD FORMING ORGANS | UNK | | | | | |
| . | . | . | . | ACETYLSALICYLIC ACID | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | |
| . | . | . | . | EUTIROX | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONE | UNK | | | | | |
| . | . | . | . | LEVOTHYROXINE | | | | | | |
| . | . | . | . | IPOTIROIDISM | | | | | | |
| . | . | . | . | MODURETIC | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | CARDIOVASCULAR SYSTEM | UNK | | | | | |
| . | . | . | . | MODURETIC | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | |
| 100350 | DROP | Female | 67 | TENORMIN | UNK | YES | 1 | 1 | DAILY | ORAL |
| . | . | . | . | CARDIOVASCULAR SYSTEM | | | | | | |
| . | . | . | . | ATENOLOL | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | |
| 100351 | GEL | Female | 79 | TRIATEC | UNK | YES | 1 | # | DAILY | ORAL |
| . | . | . | . | CARDIOVASCULAR SYSTEM | | | | | | |
| . | . | . | . | RAMIPRIL | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | |
| 100353 | GEL | Female | 72 | TOTALIP | UNK | YES | 1 | 1 | DAILY | ORAL |
| . | . | . | . | CARDIOVASCULAR SYSTEM | | | | | | |
| . | . | . | . | ATORVASTATIN | | | | | | |
| . | . | . | . | HYPERCOLESTEROLEMY | | | | | | |
| 100354 | GEL | Female | 80 | MODURETIC | UNK | YES | 1 | 1 | DAILY | ORAL |
| . | . | . | . | CARDIOVASCULAR SYSTEM | | | | | | |
| . | . | . | . | MODURETIC | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | |

Listing 16 (35 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|-----------------------|-------------------------|---------|------|-------|-------|-------|
| | | | | Sex | | | | | | | |
| 100355 | DROP | Female | 80 | ATORVASTATINA | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | 1 | DAILY | ORAL |
| . | . | . | . | ATORVASTATIN | | | | | | | |
| . | . | . | . | HYPERCOLESTEROLEMY | | | | | | | |
| 100356 | GEL | Male | 74 | ATORVASTATINA | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | 1 | DAILY | ORAL |
| . | . | . | . | ATORVASTATIN | | | | | | | |
| . | . | . | . | HYPERCOLESTEROLEMY | | | | | | | |
| . | . | . | . | BISOPROLOLO | CARDIOVASCULAR SYSTEM | UNK | YES | 1 | 1 | DAILY | ORAL |
| . | . | . | . | BISOPROLOL | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |

Listing 16 (36 of 64): Concomitant treatments

| Sbj | Study | Age | Preferred term/ Therapeutic area/ | Start date/ | End date | Ongoing | Dose | Units | Freq. | Route |
|--------|-------|--------|--------------------------------------|-----------------------------------|-----------|---------|-----------|-------|-------|-------------|
| Code | drug | Sex | (year) | Indication | | | | | | |
| 200101 | GEL | Female | 66 | ADRENALIN | 16JAN2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | | SENSORY ORGANS | 16JAN2018 | | | | | |
| . | . | . | | EPINEPHRINE | | | | | | |
| . | . | . | | DILATION | | | | | | |
| . | . | . | | ALPHAGAN | 17JAN2018 | | 1 | Drop | ONCE | OCULAR |
| . | . | . | | SENSORY ORGANS | 18JAN2018 | | | | | |
| . | . | . | | BRIMONIDINE | | | | | | |
| . | . | . | | INCREASED IOP | | | | | | |
| . | . | . | | CEFUROXIM | 16JAN2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | | ANTIINFECTIVES FOR SYSTEMIC USE | 16JAN2018 | | | | | |
| . | . | . | | CEFUROXIME | | | | | | |
| . | . | . | | ANTIBIOTIC | | | | | | |
| . | . | . | | COSOPT | 17JAN2018 | | 1 | Drop | ONCE | OCULAR |
| . | . | . | | SENSORY ORGANS | 18JAN2018 | | | | | |
| . | . | . | | COSOPT | | | | | | |
| . | . | . | | INCREASED IOP | | | | | | |
| . | . | . | | DORMICUM | 16JAN2018 | | 1,5 | mg | ONCE | INTRAVENOUS |
| . | . | . | | NERVOUS SYSTEM | 16JAN2018 | | | | | |
| . | . | . | | NITRAZEPAM | | | | | | |
| . | . | . | | SEDATION | | | | | | |
| . | . | . | | XYLONEST | 16JAN2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | | NERVOUS SYSTEM | 16JAN2018 | | | | | |
| . | . | . | | PRILOCAINE | | | | | | |
| . | . | . | | LOKAL ANESTHESIA | | | | | | |
| 200102 | DROP | Female | 76 | CANDERSATAN/HCT | UNK | YES | 16 / 12,5 | mg | DAILY | ORAL |
| . | . | . | | CARDIOVASCULAR SYSTEM | UNK | | | | | |
| . | . | . | | CANDESARTAN W/HYDROCHLOROTHIAZIDE | | | | | | |
| . | . | . | | HYPERTENSION | | | | | | |

Listing 16 (37 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|--|--|-------------------------|---------|--------|-------|-----------|--------|
| | | | | Sex | | | | | | | |
| 200103 | DROP | Male | 82 | AMLODIPIN DEXCEL CARDIOVASCULAR SYSTEM | | UNK | YES | 10 | mg | ONCE | ORAL |
| . | . | . | . | AMLODIPINE | | UNK | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | ARTELAC SENSORY ORGANS | | 14MAR2018 28MAR2018 | | 1mg/ml | Drops | AS NEEDED | OCULAR |
| . | . | . | . | HYPROMELLOSE | | | | | | | |
| . | . | . | . | DRY EYE | | | | | | | |
| . | . | . | . | BISOPROLOL RATIOPHARM CARDIOVASCULAR SYSTEM | | UNK | YES | 10 | mg | ONCE | ORAL |
| . | . | . | . | BISOPROLOL | | UNK | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | BISOPROLOLHEMIFUMARAT CARDIOVASCULAR SYSTEM | | UNK | YES | 10 | mg | ONCE | ORAL |
| . | . | . | . | BISOPROLOL | | UNK | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | CEFUXIM ANTIINFECTIVES FOR SYSTEMIC USE | | 13FEB2018 13FEB2018 | | 1,0 | ml | ONCE | OCULAR |
| . | . | . | . | CEFUXIME | | | | | | | |
| . | . | . | . | ANTIBIOTIC | | | | | | | |
| . | . | . | . | CORVO CARDIOVASCULAR SYSTEM | | UNK | YES | 20 | mg | ONCE | ORAL |
| . | . | . | . | ENALAPRIL | | UNK | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | HYDROCHLOROTHIAZID CARDIOVASCULAR SYSTEM | | UNK | YES | 25 | mg | ONCE | ORAL |
| . | . | . | . | HYDROCHLOROTHIAZIDE | | UNK | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |

Listing 16 (38 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--|-------------------------|---------|------|---------|-----------------|--------|
| | | | | Sex | | | | | | | |
| 200103 | DROP | Male | 82 | LIXIANA | BLOOD AND BLOOD FORMING ORGANS | 23MAY2016 | YES | 60 | mg | ONCE | ORAL |
| . | . | . | . | EDOXABAN | | UNK | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | NEVANAC GIVEN | SENSORY ORGANS | 28MAR2018 | 1mg/ml | | Drops | 3 TIMES PER DAY | OCULAR |
| . | . | . | . | NEPAFENAC | | 16APR2018 | | | | | |
| . | . | . | . | MACULA EDEMA | | | | | | | |
| . | . | . | . | OMEGA 3 | CARDIOVASCULAR SYSTEM | 2016 | YES | 1 | capsule | ONCE | ORAL |
| . | . | . | . | FISH OIL | | UNK | | | | | |
| . | . | . | . | PREVENTION | | | | | | | |
| . | . | . | . | TAMSULOSIN | GENITO URINARY SYSTEM AND SEX HORMONES | UNK | YES | 0,4 | mg | ONCE | ORAL |
| . | . | . | . | TAMSULOSIN | | UNK | | | | | |
| . | . | . | . | ENLARGED PROSTATE | | | | | | | |

Listing 16 (39 of 64): Concomitant treatments

| Sbj | Study | Age | Preferred term/ Therapeutic area/ | Start date/ | End date | Ongoing | Dose | Units | Freq. | Route |
|--------|-------|--------|--------------------------------------|---------------------------------|----------|---------|------|-------|-------|-------------|
| Code | drug | Sex | (year) | Indication | | | | | | |
| 200104 | GEL | Female | 78 | ADRENALIN 0,05% | 8MAY2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | . | SENSORY ORGANS | 8MAY2018 | | | | | |
| . | . | . | . | EPINEPHRINE | | | | | | |
| . | . | . | . | PUPIL DELATION | | | | | | |
| . | . | . | . | BETAVERT | 1992 | YES | 12 | mg | ONCE | ORAL |
| . | . | . | . | NERVOUS SYSTEM | UNK | | | | | |
| . | . | . | . | BETAHISTINE | | | | | | |
| . | . | . | . | LABYRINTHINE VERTIGO | | | | | | |
| . | . | . | . | CEFUXIME | 8MAY2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | . | ANTIINFECTIVES FOR SYSTEMIC USE | 8MAY2018 | | | | | |
| . | . | . | . | CEFUXIME | | | | | | |
| . | . | . | . | ANTIBIOTIC | | | | | | |
| . | . | . | . | DORMICUM | 8MAY2018 | | 1,5 | mg | ONCE | INTRAVENOUS |
| . | . | . | . | NERVOUS SYSTEM | 8MAY2018 | | | | | |
| . | . | . | . | NITRAZEPAM | | | | | | |
| . | . | . | . | SEDATION | | | | | | |
| . | . | . | . | PHENYLEPHRIN-TROPICAMID | 8MAY2018 | | 3 | drops | ONCE | OCULAR |
| . | . | . | . | SENSORY ORGANS | 8MAY2018 | | | | | |
| . | . | . | . | PHENYLEPHRINE W/TROPICAMIDE | | | | | | |
| . | . | . | . | PUPIL DILATION | | | | | | |
| . | . | . | . | PHENYLEPHRIN-TROPICAMID | 9MAY2018 | | 1 | drop | ONCE | OCULAR |
| . | . | . | . | SENSORY ORGANS | 9MAY2018 | | | | | |
| . | . | . | . | PHENYLEPHRINE W/TROPICAMIDE | | | | | | |
| . | . | . | . | PUPIL DILATION | | | | | | |
| . | . | . | . | VIGANTOLETTEN | 2015 | YES | 1000 | IE | ONCE | ORAL |
| . | . | . | . | ALIMENTARY TRACT AND METABOLISM | UNK | | | | | |
| . | . | . | . | COLECALCIFEROL | | | | | | |
| . | . | . | . | OSTEOPOROSIS | | | | | | |
| . | . | . | . | XYLONEST 1% | 8MAY2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | . | NERVOUS SYSTEM | 8MAY2018 | | | | | |
| . | . | . | . | PRLOCAINE | | | | | | |
| . | . | . | . | LOKAL ANESTHESIA | | | | | | |

Listing 16 (40 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Therapeutic area/ Indication | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|--|-------------------------|---------|-------|-------|---------------|-------------|
| 200105 | GEL | Female 65 | ADRENALIN | 29MAY2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | SENSORY ORGANS | 29MAY2018 | | | | | |
| . | . | . | EPINEPHRINE | | | | | | |
| . | . | . | PUPIL DILATION | | | | | | |
| . | . | . | ASS 100 | 2010 | YES | 100 | mg | ONCE | ORAL |
| . | . | . | BLOOD AND BLOOD FORMING ORGANS | UNK | | | | | |
| . | . | . | ACETYLSALICYLIC ACID | | | | | | |
| . | . | . | HYPERTENSION | | | | | | |
| . | . | . | ATROVASTATIN | UNK | YES | 20 | mg | ONCE | ORAL |
| . | . | . | CARDIOVASCULAR SYSTEM | UNK | | | | | |
| . | . | . | ATORVASTATIN | | | | | | |
| . | . | . | HYPERCOLESTEROLEMIA | | | | | | |
| . | . | . | CEFUROXIM | 29MAY2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | ANTIINFECTIVES FOR SYSTEMIC USE | 29MAY2018 | | | | | |
| . | . | . | CEFUROXIME | | | | | | |
| . | . | . | ANTIBIOTIC | | | | | | |
| . | . | . | DORMICUM | 29MAY2018 | | 1,5 | mg | ONCE | INTRAVENOUS |
| . | . | . | NERVOUS SYSTEM | 29MAY2018 | | | | | |
| . | . | . | NITRAZEPAM | | | | | | |
| . | . | . | SEDATION | | | | | | |
| . | . | . | METROPOLOL | 2010 | YES | 23,75 | mg | TWICE PER DAY | ORAL |
| . | . | . | CARDIOVASCULAR SYSTEM | UNK | | | | | |
| . | . | . | METOPROLOL | | | | | | |
| . | . | . | HYPERTENSION | | | | | | |
| . | . | . | VALSARTAN | 2010 | YES | 40 | mg | ONCE | ORAL |
| . | . | . | CARDIOVASCULAR SYSTEM | UNK | | | | | |
| . | . | . | VALSARTAN | | | | | | |
| . | . | . | HYPERTENSION | | | | | | |
| . | . | . | XYLONEST | 29MAY2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | NERVOUS SYSTEM | 29MAY2018 | | | | | |
| . | . | . | PRILLOCAINE | | | | | | |
| . | . | . | LOKAL ANESTHESIA | | | | | | |

Listing 16 (41 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Sex | Preferred term/ Indication | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-----|---|-------------------------|---------|---------|-------|-------|-------------|
| 200106 | DROP | Female 75 | | ASS 100 | UNK | YES | 100 | mg | ONCE | ORAL |
| . | . | | | BLOOD AND BLOOD FORMING ORGANS | UNK | | | | | |
| . | . | | | ACETYLSALICYLIC ACID | | | | | | |
| . | . | | | HYPERTENSION | | | | | | |
| . | . | | | CEFUROXIME | 26JUN2018 | | 1 | ml | ONCE | OCULAR |
| . | . | | | ANTIINFECTIVES FOR SYSTEMIC USE | 26JUN2018 | | | | | |
| . | . | | | CEFUROXIME | | | | | | |
| . | . | | | ANTIBIOTIC | | | | | | |
| . | . | | | DORMICUM | 26JUN2018 | | 1 , 5 | mg | ONCE | INTRAVENOUS |
| . | . | | | NERVOUS SYSTEM | 26JUN2018 | | | | | |
| . | . | | | NITRAZEPAM | | | | | | |
| . | . | | | SEDATION | | | | | | |
| . | . | | | FOSINORM | UNK | YES | 20 | mg | ONCE | ORAL |
| . | . | | | CARDIOVASCULAR SYSTEM | UNK | | | | | |
| . | . | | | FOSINOPRIL | | | | | | |
| . | . | | | HYPERTENSION | | | | | | |
| . | . | | | JANUVIA | UNK | YES | 50 | mg | ONCE | ORAL |
| . | . | | | ALIMENTARY TRACT AND METABOLISM | UNK | | | | | |
| . | . | | | SITAGLIPTIN | | | | | | |
| . | . | | | DIABETIS | | | | | | |
| . | . | | | L-THYROXIN | UNK | YES | 0 , 075 | mg | ONCE | ORAL |
| . | . | | | SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONE | UNK | | | | | |
| . | . | | | LEVOTHYROXINE | | | | | | |
| . | . | | | HYPOTHYROIDISM | | | | | | |

Listing 16 (42 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|-------------------------|---------|-------|-------|---------------|--------|
| 200106 | DROP | Female 75 | METFORMIN | ALIMENTARY TRACT AND METABOLISM | UNK | YES | 500 | mg | TWICE PER DAY | ORAL |
| . | . | . | METFORMIN | DIABETIS | UNK | | | | | |
| . | . | . | METROPROLOL SUCCINAT TAD | CARDIOVASCULAR SYSTEM | UNK | YES | 23,75 | mg | TWICE PER DAY | ORAL |
| . | . | . | METOPROLOL | HYPERTENSION | UNK | | | | | |
| . | . | . | VIGANTOLETTEN | ALIMENTARY TRACT AND METABOLISM | UNK | YES | 1000 | IE | ONCE | ORAL |
| . | . | . | COLECALCIFEROL | PREVENTION | UNK | | | | | |
| . | . | . | VITAMIN B12 | BLOOD AND BLOOD FORMING ORGANS | UNK | YES | 400 | mg | ONCE | ORAL |
| . | . | . | HYDROXOCOBALAMIN | HYDROXOCOBALAMIN | UNK | | | | | |
| . | . | . | VITAMIN B12 DEFICIENCY | VITAMIN B12 DEFICIENCY | | | | | | |
| . | . | . | XYLONDEST | NERVOUS SYSTEM | 26JUN2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | PRILOCAINE | LOKAL ANESTHESIA | 26JUN2018 | | | | | |

Listing 16 (43 of 64): Concomitant treatments

| Sbj | Study | Age | Preferred term/ Therapeutic area/ | Start date/ | End date | Ongoing | Dose | Units | Freq. | Route |
|--------|-------|--------|--------------------------------------|---------------------------------|----------|---------|------|-------|---------------|-------------|
| Code | drug | Sex | (year) | Indication | | | | | | |
| 200107 | DROP | Female | 54 | CEFUROXIME | 3JUL2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | | ANTIINFECTIVES FOR SYSTEMIC USE | 3JUL2018 | | | | | |
| . | . | . | | CEFUROXIME | | | | | | |
| . | . | . | | ANTIBIOTIC | | | | | | |
| . | . | . | | CETIRIZIN | UNK | YES | 10 | mg | TWICE PER DAY | ORAL |
| . | . | . | | RESPIRATORY SYSTEM | UNK | | | | | |
| . | . | . | | CETIRIZINE | | | | | | |
| . | . | . | | ALLERGICAL REACTIONS | | | | | | |
| . | . | . | | DORMICUM | 3JUN2018 | | 1,5 | mg | ONCE | INTRAVENOUS |
| . | . | . | | NERVOUS SYSTEM | 3JUL2018 | | | | | |
| . | . | . | | NITRAZEPAM | | | | | | |
| . | . | . | | SEDATION | | | | | | |
| . | . | . | | DORMICUM | 3JUL2018 | | 1,5 | mg | ONCE | INTRAVENOUS |
| . | . | . | | NERVOUS SYSTEM | 3JUL2018 | | | | | |
| . | . | . | | NITRAZEPAM | | | | | | |
| . | . | . | | SEDATION | | | | | | |
| . | . | . | | FENTANYL HXAL | UNK | YES | 100 | pg/h | AS NEEDED | ORAL |
| . | . | . | | NERVOUS SYSTEM | UNK | | | | | |
| . | . | . | | FENTANYL | | | | | | |
| . | . | . | | PAIN | | | | | | |
| . | . | . | | FENTANYL PERORAL | UNK | YES | 0,2 | mg | AS NEEDED | ORAL |
| . | . | . | | NERVOUS SYSTEM | UNK | | | | | |
| . | . | . | | FENTANYL | | | | | | |
| . | . | . | | PAIN | | | | | | |

Listing 16 (44 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|--|-------------------------------------|--|-------------------------|---------|-------|-------|-----------------|--------------|
| | | | | Sex | | | | | | | |
| 200107 | DROP | Female 54 | FUROSEMID CARDIOVASCULAR SYSTEM | | | UNK | YES | 40 | mg | AS NEEDED | ORAL |
| . | . | . | FUROSEMIDE HYPERTENSION | | | UNK | | | | | |
| . | . | . | GLIVEC ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS | | | UNK | YES | 100 | mg | TWICE PER DAY | ORAL |
| . | . | . | IMATINIB SYSTEMIC MASTOCYTOSIS | | | UNK | | | | | |
| . | . | . | INSUMAN BASAL ALIMENTARY TRACT AND METABOLISM | | | UNK | YES | 40-45 | I.E. | 3 TIMES PER DAY | SUBCUTANEOUS |
| . | . | . | INSULIN HUMAN DIABETIS | | | UNK | | | | | |
| . | . | . | LACTULOSE SIRUP ALIMENTARY TRACT AND METABOLISM | | | UNK | YES | 1 | ml | AS NEEDED | ORAL |
| . | . | . | LACTULOSE CONSTIPATION | | | UNK | | | | | |
| . | . | . | NITROLINGUAL AKUT SPRAY CARDIOVASCULAR SYSTEM | | | UNK | YES | 1 | humb | AS NEEDED | ORAL |
| . | . | . | GLYCERYL TRINITRATE ASTHMA | | | UNK | | | | | |
| . | . | . | PHENYLEPHRIN-TROPICAMID SENSORY ORGANS | | | 4JUL2018 | | 1 | drop | ONCE | OCULAR |
| . | . | . | PHENYLEPHRINE W/TROPICAMIDE PUPIL DILATION | | | 4JUL2018 | | | | | |
| . | . | . | PREDNISOLON SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONE | | | UNK | YES | 10 | mg | TWICE PER DAY | ORAL |
| . | . | . | PREDNISOLONE SYSTEMIC MASTCYTOSIS | | | UNK | | | | | |
| . | . | . | XYLONEST NERVOUS SYSTEM | | | 3JUL2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | PRILOCAINE LOKAL ANESTHESIA | | | 3JUL2018 | | | | | |

Listing 16 (45 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Sex | Reported term/ Therapeutic area/ Preferred term/ Indication | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|------|---|-------------------------|---------|-------|-------|-------|-------------|
| 200108 | GEL | 77 | Male | ALLOPURINOL MUSCULO-SKELETAL SYSTEM ALLOPURINOL ELEVATED URIC ACID LEVEL | 2008 | YES | 150 | mg | ONCE | ORAL |
| . | . | . | . | AMLO CARDIOVASCULAR SYSTEM AMLODIPINE HIGH BLODDPRESSURE | 2008 | YES | 5 | mg | ONCE | ORAL |
| . | . | . | . | ASS 100 BLOOD AND BLOOD FORMING ORGANS ACETYLSALICYLIC ACID PREVENTION | 2008 | YES | 100 | mg | ONCE | ORAL |
| . | . | . | . | CANDESARTAN CARDIOVASCULAR SYSTEM CANDESARTAN HIGH BLOODPRESSURE | 2008 UNK | YES | 8 | mg | ONCE | ORAL |
| . | . | . | . | CEFUROXIM ANTIINFECTIVES FOR SYSTEMIC USE CEFUROXIME ANTIBIOTIC | 4SEP2018 4SEP2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | . | DORMICUM NERVOUS SYSTEM NITRAZEPAM SEDATION | 4SEP2018 4SEP2018 | | 1 , 5 | mg | ONCE | INTRAVENOUS |

Listing 16 (46 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|---|-------------------------|---------|------|------------|-------|--------|
| | | | | Sex | | | | | | | |
| 200108 | GEL | Male | 77 | METROPOLOL | CARDIOVASCULAR SYSTEM | 2008 | YES | 47,5 | mg | ONCE | ORAL |
| . | . | . | . | METOPROLOL | | | | | | | |
| . | . | . | . | HIGH BLOODPRESSURE | | | | | | | |
| . | . | . | . | SIMVA | CARDIOVASCULAR SYSTEM | UNK | YES | 40 | mg | ONCE | ORAL |
| . | . | . | . | SIMVASTATIN | | | | | | | |
| . | . | . | . | HIGH BLOODPRESSURE | | | | | | | |
| . | . | . | . | THYROXIN | SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONE | UNK | YES | 50 | microgramm | ONCE | ORAL |
| . | . | . | . | LEVOTHYROXINE | | | | | | | |
| . | . | . | . | HYPOTHYROIDISM | | | | | | | |
| . | . | . | . | XYLONEST 1% | NERVOUS SYSTEM | 4SEP2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | . | PRILOCaine | | 4SEP2018 | | | | | |
| . | . | . | . | ANESTHESIA | | | | | | | |

Listing 16 (47 of 64): Concomitant treatments

| Sbj Code | Study drug | Age Sex (year) | Reported term/ Therapeutic area/ Preferred term/ Indication | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|----------------------|--|-------------------------|---------|------|-------|-----------|-------------|
| 200109 | GEL | Female 84 | ALENDROVIS (ALENDRONACID) MUSCULO-SKELETAL SYSTEM ALENDRONIC ACID OSTEOPOROSIS (FREQUENCY ONCE/WEEK) | 1998 | YES | 70 | mg | AS NEEDED | ORAL |
| . | . | . | CALCIUM ALIMENTARY TRACT AND METABOLISM CALCIUM GLUCONATE OSTEOPOROSIS | 1998 | YES | 500 | mg | ONCE | ORAL |
| . | . | . | CEFUROXIME ANTIINFECTIVES FOR SYSTEMIC USE CEFUROXIME ANTIBIOTIC | 20OCT2018 20OCT2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | DORMICUM NERVOUS SYSTEM NITRAZEPAM SEDATION | 20OCT2018 20OCT2018 | | 1,5 | mg | ONCE | INTRAVENOUS |
| . | . | . | INFLANEFRAN FORTE SENSORY ORGANS PREDNISOLONE AGAINST INFLAMMATION (HOURLY) | 3OCT2018 5OCT2018 | | 1 | Drop | AS NEEDED | OCULAR |
| . | . | . | INFLANEFRAN FORTE SENSORY ORGANS PREDNISOLONE AGAINST INFLAMMATION (5TIMES A DAY) | 5OCT2018 12OCT2018 | | 1 | Drop | AS NEEDED | OCULAR |

Listing 16 (48 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|--|-------------------------------------|--|-------------------------|---------|------|-------|-----------------|--------|
| | | | | Sex | | | | | | | |
| 200109 | GEL | Female 84 | INFLANEFRAN FORTE SENSORY ORGANS PREDNISOLONE AGAINST INFLAMMATION | | | 13OCT2018 19OCT2018 | | 1 | drop | 4 TIMES PER DAY | OCULAR |
| . | . | . | INFLANEFRAN FORTE SENSORY ORGANS PREDNISOLONE AGAINST INFLAMMATION | | | 20OCT2018 26OCT2018 | | 1 | Drop | 3 TIMES PER DAY | OCULAR |
| . | . | . | INFLANEFRAN FORTE SENSORY ORGANS PREDNISOLONE AGAINST INFLAMMATION | | | 27OCT2018 2NOV2018 | | 1 | Drop | TWICE PER DAY | OCULAR |
| . | . | . | INFLANEFRAN FORTE SENSORY ORGANS PREDNISOLONE AGAINST INFLAMMATION | | | 3NOV2018 9NOV2018 | | 1 | Drop | ONCE | OCULAR |
| . | . | . | METROPOLO CARDIOVASCULAR SYSTEM METOPROLOL HEART RHYTHM DISTURBANCES | | | 1990 | YES | 50 | mg | TWICE PER DAY | ORAL |
| . | . | . | MOVICOL ALIMENTARY TRACT AND METABOLISM MOVICOL CONSTIPATION | | | UNK | YES | 1 | bag | ONCE | ORAL |
| . | . | . | PHENYLEPHRIN TROPICAMID SENSORY ORGANS PHENYLEPHRINE W/TROPICAMIDE PUPIL DILATION | | | 3OCT2018 3OCT2018 | | 1 | Drop | ONCE | OCULAR |
| . | . | . | RAMIPRIL CARDIOVASCULAR SYSTEM RAMIPRIL HIGH BLOODPRESSURE | | | UNK | YES | 2,5 | mg | ONCE | ORAL |
| . | . | . | SIMVASTATIN CARDIOVASCULAR SYSTEM SIMVASTATIN | | | 2008 | YES | 20 | mg | TWICE PER DAY | ORAL |

HIGH BLOODPRESSURE

Listing 16 (49 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|-----------------------|-------------------------|---------|------|-------|---------------|--------|
| | | | | Sex | | | | | | | |
| 200109 | GEL | Female | 84 | VERAPAMIL | CARDIOVASCULAR SYSTEM | 1990 | YES | 120 | mg | TWICE PER DAY | ORAL |
| . | . | . | . | VERAPAMIL | | | | | | | |
| . | . | . | . | HEART RHYTHM DISTURBANCES | | | | | | | |
| . | . | . | . | XYLONEST 1% | | 20OCT2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | . | NERVOUS SYSTEM | | 2OCT2018 | | | | | |
| . | . | . | . | PRILOCaine | | | | | | | |
| . | . | . | . | ANESTHESIA | | | | | | | |

Listing 16 (50 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--|-------------------------|---------|-----------|-------|-----------------|-------------|
| | | | | Sex | | | | | | | |
| 200110 | DROP | Male | 64 | AZOPT | | 17OCT2018 | YES | 1 | Drop | TWICE PER DAY | OCULAR |
| . | . | . | | SENSORY ORGANS | | | | | | | |
| . | . | . | | BRINZOLAMIDE | | | | | | | |
| . | . | . | | ARTERY OCCLUSION AND PERFUSION | | | | | | | |
| . | . | . | | BERODUAL N | | UNK | YES | 0,02-0,04 | mg | AS NEEDED | ORAL |
| . | . | . | | RESPIRATORY SYSTEM | | | | | | | |
| . | . | . | | DUOVENT | | | | | | | |
| . | . | . | | COPD | | | | | | | |
| . | . | . | | CEFUROXIME | | 9OCT2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | | ANTIINFECTIVES FOR SYSTEMIC USE | | 9OCT2018 | | | | | |
| . | . | . | | CEFUROXIME | | | | | | | |
| . | . | . | | ANTIBIOTIC | | | | | | | |
| . | . | . | | DORMICUM | | 9OCT2018 | | 1,5 | mg | ONCE | INTRAVENOUS |
| . | . | . | | NERVOUS SYSTEM | | 9OCT2018 | | | | | |
| . | . | . | | NITRAZEPAM | | | | | | | |
| . | . | . | | SEDATION | | | | | | | |
| . | . | . | | HYLOGEL | | 21OCT2018 | | 1 | Drop | AS NEEDED | OCULAR |
| . | . | . | | SENSORY ORGANS | | 30OCT2018 | | | | | |
| . | . | . | | HYALURONIC ACID | | | | | | | |
| . | . | . | | AS NEEDED MEANS 5 TIMES PER DAY | | | | | | | |
| . | . | . | | INFLANEFRAN FORTE | | 17OCT2018 | | 1 | Drop | 4 TIMES PER DAY | OCULAR |
| . | . | . | | SENSORY ORGANS | | 20OCT2018 | | | | | |
| . | . | . | | PREDNISOLONE | | | | | | | |
| . | . | . | | ARTERY OCCLUSION | | | | | | | |

Listing 16 (51 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--|-------------------------|---------|-------|-------|---------------|--------|
| | | | | Sex | | | | | | | |
| 200110 | DROP | Male | 64 | INFLANEFRAN FORTE | | 23OCT2018 | | 1 | Drop | TWICE PER DAY | OCULAR |
| . | . | . | | SENSORY ORGANS | | 30OCT2018 | | | | | |
| . | . | . | | PREDNISOLONE | | | | | | | |
| . | . | . | | ARTERY OCCLUSION | | | | | | | |
| . | . | . | | LERCANIDIPIN | | UNK | YES | 18,88 | mg | ONCE | ORAL |
| . | . | . | | CARDIOVASCULAR SYSTEM | | | | | | | |
| . | . | . | | LERCANIDIPINE | | | | | | | |
| . | . | . | | HIGH BLOODPRESSURE | | | | | | | |
| . | . | . | | PHENYLEPHRIN-TROPICAMID | | 10OCT2018 | | 1 | Drop | ONCE | OCULAR |
| . | . | . | | SENSORY ORGANS | | 10OCT2018 | | | | | |
| . | . | . | | PHENYLEPHRINE W/TROPICAMIDE | | | | | | | |
| . | . | . | | PUPIL DILATION | | | | | | | |
| . | . | . | | RAMIPRIL | | UNK | YES | 5 | mg | TWICE PER DAY | ORAL |
| . | . | . | | CARDIOVASCULAR SYSTEM | | | | | | | |
| . | . | . | | RAMIPRIL | | | | | | | |
| . | . | . | | HIGH BLOODPRESSURE | | | | | | | |
| . | . | . | | SPIOCTO RESPIMAT | | UNK | YES | 2,5 | µg | TWICE PER DAY | NASAL |
| . | . | . | | RESPIRATORY SYSTEM | | | | | | | |
| . | . | . | | TIOTROPIUM | | | | | | | |
| . | . | . | | COPD | | | | | | | |

Listing 16 (52 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--|-------------------------|---------|-------|-------|---------------|--------|
| | | | | Sex | | | | | | | |
| 200111 | GEL | Male | 73 | ADRENALIN 0,05% | | 6NOV2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | . | SENSORY ORGANS | | 6NOV2018 | | | | | |
| . | . | . | . | EPINEPHRINE | | | | | | | |
| . | . | . | . | PUPIL-DILATION | | | | | | | |
| . | . | . | . | ALKALA N | | UNK | YES | 3 | gr | ONCE | ORAL |
| . | . | . | . | ALIMENTARY TRACT AND METABOLISM | | | | | | | |
| . | . | . | . | ALKALA N | | | | | | | |
| . | . | . | . | HEARTBURN | | | | | | | |
| . | . | . | . | ALLOPORINOL | | UNK | YES | 100 | mg | ONCE | ORAL |
| . | . | . | . | MUSCULO-SKELETAL SYSTEM | | | | | | | |
| . | . | . | . | ALLOPURINOL | | | | | | | |
| . | . | . | . | GOUT | | | | | | | |
| . | . | . | . | ALPHALIPONSÄURE | | UNK | YES | 600 | mg | ONCE | ORAL |
| . | . | . | . | ALIMENTARY TRACT AND METABOLISM | | | | | | | |
| . | . | . | . | THIOCTIC ACID | | | | | | | |
| . | . | . | . | INDISPOSITION | | | | | | | |
| . | . | . | . | BASOSYX | | UNK | YES | 432,5 | mg | TWICE PER DAY | ORAL |
| . | . | . | . | VARIOUS | | | | | | | |
| . | . | . | . | GENERAL NUTRIENTS | | | | | | | |
| . | . | . | . | ACID-BASE-BALANCE | | | | | | | |
| . | . | . | . | CANDERSATAN | | 2017 | YES | 16 | mg | TWICE PER DAY | ORAL |
| . | . | . | . | CARDIOVASCULAR SYSTEM | | | | | | | |
| . | . | . | . | CANDESARTAN | | | | | | | |
| . | . | . | . | HIGH BLOODPRESSURE | | | | | | | |
| . | . | . | . | CEFUROXIME | | 6NOV2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | . | ANTIINFECTIVES FOR SYSTEMIC USE | | 6NOV2018 | | | | | |
| . | . | . | . | CEFUROXIME | | | | | | | |
| . | . | . | . | ANTIBIOTIC | | | | | | | |

Listing 16 (53 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--|-------------------------|---------|------|-------|-----------------|-------------|
| | | | | Sex | | | | | | | |
| 200111 | GEL | Male | 73 | CORNEREGEL | | 6NOV2018 | | 1 | Drop | ONCE | OCULAR |
| . | . | . | . | SENSORY ORGANS | | 6NOV2018 | | | | | |
| . | . | . | . | DEXPANTHENOL | | | | | | | |
| . | . | . | . | FOREIGN BODY SENSATION | | | | | | | |
| . | . | . | . | DORMICUM | | 6NOV2018 | | 1,5 | mg | ONCE | INTRAVENOUS |
| . | . | . | . | NERVOUS SYSTEM | | 6NOV2018 | | | | | |
| . | . | . | . | NITRAZEPAM | | | | | | | |
| . | . | . | . | SEDATION | | | | | | | |
| . | . | . | . | GRANUFINK | | UNK | YES | 500 | mg | ONCE | ORAL |
| . | . | . | . | VARIOUS | | | | | | | |
| . | . | . | . | CUCURBITA PEPO | | | | | | | |
| . | . | . | . | BLADDER DISCOMFORT | | | | | | | |
| . | . | . | . | PANTOPRAZOL | | UNK | YES | 20 | mg | ONCE | ORAL |
| . | . | . | . | ALIMENTARY TRACT AND METABOLISM | | | | | | | |
| . | . | . | . | PANTOPRAZOLE | | | | | | | |
| . | . | . | . | STOMACH PAIN | | | | | | | |
| . | . | . | . | PHENYLEPHRIN-TROPICAMID | | 7NOV2018 | | 1 | Drop | ONCE | OCULAR |
| . | . | . | . | SENSORY ORGANS | | 7NOV2018 | | | | | |
| . | . | . | . | PHENYLEPHRINE W/TROPICAMIDE | | | | | | | |
| . | . | . | . | PUPIL-DILATION | | | | | | | |
| . | . | . | . | Q 10 SANOMIT | | UNK | YES | 4 | ml | 4 TIMES PER DAY | ORAL |
| . | . | . | . | ALIMENTARY TRACT AND METABOLISM | | | | | | | |
| . | . | . | . | UBIDECARENONE | | | | | | | |
| . | . | . | . | Q10 DEFICIENCY | | | | | | | |
| . | . | . | . | TIMOLOL 0,5% | | 6NOV2018 | | 1 | Drop | ONCE | OCULAR |
| . | . | . | . | SENSORY ORGANS | | 6NOV2018 | | | | | |
| . | . | . | . | TIMOLOL | | | | | | | |
| . | . | . | . | IOP REDUCTION | | | | | | | |
| . | . | . | . | VITAMIN B12 | | UNK | YES | 1 | ml | AS NEEDED | ORAL |
| . | . | . | . | BLOOD AND BLOOD FORMING ORGANS | | | | | | | |
| . | . | . | . | HYDROXOCOBALAMIN | | | | | | | |
| . | . | . | . | VITAMIN B12 DEFICIENCY | | | | | | | |

Listing 16 (54 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Therapeutic area/ Indication | Reported term/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|--|----------------------------|------------|-------------------------|---------|------|-------|-------|--------|
| | | | | Sex | Indication | | | | | | |
| 200111 | GEL | Male | 73 | XYLONEST NERVOUS SYSTEM | | 6NOV2018 6NOV2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | . | PRILOCaine | | | | | | | |
| . | . | . | . | ANESTHESIA | | | | | | | |

Listing 16 (55 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|---|--|-------------------------|---------|------|-------|-----------|-------------|
| | | | | Sex | | | | | | | |
| 200112 | DROP | Male | 85 | CEFUROXIME | | 13NOV2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | | ANTIINFECTIVES FOR SYSTEMIC USE | | 13NOV2018 | | | | | |
| . | . | . | | CEFUXOME | | | | | | | |
| . | . | . | | ANTIBIOTIC | | | | | | | |
| . | . | . | | DORMICUM | | 13NOV2018 | | 1,5 | mg | ONCE | INTRAVENOUS |
| . | . | . | | NERVOUS SYSTEM | | 13NOV2018 | | | | | |
| . | . | . | | NITRAZEPAM | | | | | | | |
| . | . | . | | SEDATION | | | | | | | |
| . | . | . | | HYLO PARIN EYE DROPS | | 30NOV2018 | | 1 | Drop | AS NEEDED | OCULAR |
| . | . | . | | SENSORY ORGANS | | 5DEC2018 | | | | | |
| . | . | . | | HYLO PARIN | | | | | | | |
| . | . | . | | FOREIGN BODY SENSATION, AS NEEDE MEANS 5 TIMES /D Y | | | | | | | |
| . | . | . | | LISILICH COMP | | 2006 | YES | 20 | mg | ONCE | ORAL |
| . | . | . | | CARDIOVASCULAR SYSTEM | | | | | | | |
| . | . | . | | CARACE PLUS | | | | | | | |
| . | . | . | | HIGH BLOODPRESSURE | | | | | | | |
| . | . | . | | PHENYLEPHRIN-TROPICAMID | | 14NOV2018 | | 1 | Drop | ONCE | OCULAR |
| . | . | . | | SENSORY ORGANS | | 14NOV2018 | | | | | |
| . | . | . | | PHENYLEPHRINE W/TROPICAMIDE | | | | | | | |
| . | . | . | | PUPIL-DILATION | | | | | | | |
| . | . | . | | XYLONEST 1% | | 13NOV2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | | NERVOUS SYSTEM | | 13NOV2018 | | | | | |
| . | . | . | | PRILOCaine | | | | | | | |
| . | . | . | | ANESTHESIA | | | | | | | |

Listing 16 (56 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--|-------------------------|---------|------|-------|-----------------|-------------|
| | | | | Sex | | | | | | | |
| 200113 | DROP | Male | 77 | ASS 100 | | 2013 | YES | 100 | mg | ONCE | ORAL |
| . | . | . | | BLOOD AND BLOOD FORMING ORGANS | | | | | | | |
| . | . | . | | ACETYLSALICYLIC ACID | | | | | | | |
| . | . | . | | CIRCULATORY DISORDER | | | | | | | |
| . | . | . | | ATORVASTATIN | | UNK | YES | 10 | mg | ONCE | ORAL |
| . | . | . | | CARDIOVASCULAR SYSTEM | | | | | | | |
| . | . | . | | ATORVASTATIN | | | | | | | |
| . | . | . | | CHOLESTEROL | | | | | | | |
| . | . | . | | CEFUROXIME | | 13NOV2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | | ANTIINFECTIVES FOR SYSTEMIC USE | | 13NOV2018 | | | | | |
| . | . | . | | CEFUROXIME | | | | | | | |
| . | . | . | | ANTIBIOTIC | | | | | | | |
| . | . | . | | DORMICUM | | 13NOV2018 | | 1,5 | mg | ONCE | INTRAVENOUS |
| . | . | . | | NERVOUS SYSTEM | | 13NOV2018 | | | | | |
| . | . | . | | NITRAZEPAM | | | | | | | |
| . | . | . | | SEDATION | | | | | | | |
| . | . | . | | ESCITALOPRAM | | 20OCT2017 | YES | 5 | mg | ONCE | ORAL |
| . | . | . | | NERVOUS SYSTEM | | | | | | | |
| . | . | . | | ESCITALOPRAM | | | | | | | |
| . | . | . | | DEPRESSION | | | | | | | |
| . | . | . | | FLOXAL | | 21NOV2018 | | 1 | Drop | 3 TIMES PER DAY | TRANSDERMAL |
| . | . | . | | SENSORY ORGANS | | 28DEC2018 | | | | | |
| . | . | . | | OFLOXACIN | | | | | | | |
| . | . | . | | HORDEOLUM | | | | | | | |

Listing 16 (57 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|----------------|-------------------------|---------|------|-------|---------------|--------|
| | | | | Sex | | | | | | | |
| 200113 | DROP | Male | 77 | OLANZAPIN | NERVOUS SYSTEM | DEC2017 | YES | 2,5 | mg | TWICE PER DAY | ORAL |
| . | . | . | . | OLANZAPINE | | | | | | | |
| . | . | . | . | DEPRESSION | | | | | | | |
| . | . | . | . | PHENYLEPHRIN-TROPICAMID | SENSORY ORGANS | 13NOV2018 | | 2 | Drops | ONCE | OCULAR |
| . | . | . | . | PHENYLEPHRINE W/TROPICAMIDE | PUPIL-DILATION | 13NOV2018 | | | | | |
| . | . | . | . | PHENYLEPHRIN-TROPICAMID | SENSORY ORGANS | 14NOV2018 | | 1 | Drop | ONCE | OCULAR |
| . | . | . | . | PHENYLEPHRINE W/TROPICAMIDE | PUPIL-DILATION | 14NOV2018 | | | | | |
| . | . | . | . | XYLONEST | ANESTHESIA | 13NOV2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | . | NERVOUS SYSTEM | PRILOCaine | 13NOV2018 | | | | | |
| . | . | . | . | ANESTHESIA | | | | | | | |

Listing 16 (58 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|---------------------------------|-------------------------|---------|------|-------|---------------|-------------|
| | | | | Sex | | | | | | | |
| 200114 | DROP | Female 64 | ALLOPURINOL | | MUSCULO-SKELETAL SYSTEM | 2008 | YES | 100 | mg | ONCE | ORAL |
| . | . | . | ALLOPURINOL | | GOUT | | | | | | |
| . | . | . | AMLODIPIN | | CARDIOVASCULAR SYSTEM | 2008 | YES | 10 | mg | TWICE PER DAY | ORAL |
| . | . | . | AMLODIPINE | | HIGH BLOODPRESSURE | | | | | | |
| . | . | . | CEFUXOME | | ANTIINFECTIVES FOR SYSTEMIC USE | 27NOV2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | CEFUXOME | | ANTIBIOTIC | 27NOV2018 | | | | | |
| . | . | . | DEXAGEL | | SENSORY ORGANS | 27NOV2018 | | 1 | Drop | ONCE | OCULAR |
| . | . | . | DEXAMETHASONE | | ANTIFLAMATORY | 27NOV2018 | | | | | |
| . | . | . | DORMICUM | | NERVOUS SYSTEM | 27NOV2018 | | 1,5 | mg | ONCE | INTRAVENOUS |
| . | . | . | NITRAZEPAM | | SEDATION | 27NOV2018 | | | | | |
| . | . | . | HYDROCHLOROTIAZID | | CARDIOVASCULAR SYSTEM | 2008 | YES | 25 | mg | ONCE | ORAL |
| . | . | . | HYDROCHLOROTHIAZIDE | | HIGH BLOODPRESSURE | | | | | | |

Listing 16 (59 of 64): Concomitant treatments

| Sbj Code | Study drug | Age Sex (year) | Reported term/ Therapeutic area/ Preferred term/ Indication | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|----------------------|--|-------------------------|---------|------|-------|---------------|--------|
| 200114 | DROP | Female 64 | METFORMINHYDROCHLORID ALIMENTARY TRACT AND METABOLISM METFORMIN DIABETIS MELLITUS | 2015 | YES | 1000 | mg | TWICE PER DAY | ORAL |
| . | . | . | METOPROLOL CARDIOVASCULAR SYSTEM METOPROLOL HIGH BLOODPRESSURE | 2008 | YES | 200 | mg | TWICE PER DAY | ORAL |
| . | . | . | PHENYLEPHRIN-TROPICAMID SENSORY ORGANS PHENYLEPHRINE W/TROPICAMIDE PUPIL-DILATION | 28NOV2018 28NOV2018 | | 1 | Drop | ONCE | OCULAR |
| . | . | . | RAMIPRIL CARDIOVASCULAR SYSTEM RAMIPRIL ARTERIAL HYPERTENSION | 2008 | YES | 5 | mg | TWICE PER DAY | ORAL |
| . | . | . | SITAGUPTIN ALIMENTARY TRACT AND METABOLISM SITAGLIPTIN DIABETIS MELLITUS | 2015 | YES | 50 | mg | TWICE PER DAY | ORAL |
| . | . | . | XYLONEST NERVOUS SYSTEM PRILOCAINE ANESTHESIA | 27NOV2018 27NOV2018 | | 1 | ml | ONCE | OCULAR |

Listing 16 (60 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Sex | Reported term/ Therapeutic area/ Preferred term/ Indication | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-----|--|-------------------------|---------|------|-------|---------------|-------------|
| | | | | | | | | | | |
| 200115 | GEL | Female | 70 | ADRENALIN | 18DEC2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | . | SENSORY ORGANS | 18DEC2018 | | | | | |
| . | . | . | . | EPINEPHRINE | | | | | | |
| . | . | . | . | DILATION | | | | | | |
| . | . | . | . | CEFUROXIME | 18DEC2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | . | ANTIINFECTIVES FOR SYSTEMIC USE | 18DEC2018 | | | | | |
| . | . | . | . | CEFUROXIME | | | | | | |
| . | . | . | . | ANTIBIOTIC | | | | | | |
| . | . | . | . | DORMICUM | 18DEC2018 | | 1,5 | mg | ONCE | INTRAVENOUS |
| . | . | . | . | NERVOUS SYSTEM | 18DEC2018 | | | | | |
| . | . | . | . | NITRAZEPAM | | | | | | |
| . | . | . | . | SEDATION | | | | | | |
| . | . | . | . | NOVAMINSULFON | 2017 | YES | 500 | mg | TWICE PER DAY | ORAL |
| . | . | . | . | NERVOUS SYSTEM | | | | | | |
| . | . | . | . | METAMIZOLE | | | | | | |
| . | . | . | . | ANALGESICS | | | | | | |
| . | . | . | . | PANTOPRACOL | 2012 | YES | 40 | mg | ONCE | ORAL |
| . | . | . | . | ALIMENTARY TRACT AND METABOLISM | | | | | | |
| . | . | . | . | PANTOPRAZOLE | | | | | | |
| . | . | . | . | REFLUX ESOPHAGITIS | | | | | | |
| . | . | . | . | PEHYLEPHRINTROPICAMID | 18DEC2018 | | 2 | Drops | ONCE | OCULAR |
| . | . | . | . | SENSORY ORGANS | 18DEC2018 | | | | | |
| . | . | . | . | PHENYLEPHRINE W/TROPICAMIDE | | | | | | |
| . | . | . | . | DILATION | | | | | | |

Listing 16 (61 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|-------------------------------------|--|-------------------------|---------|------|-------|-------|--------|
| | | | | Sex | | | | | | | |
| 200115 | GEL | Female | 70 | PHENYLEPHRINTROPICAMID | | 19DEC2018 | | 1 | Drop | ONCE | OCULAR |
| . | . | . | . | SENSORY ORGANS | | 19DEC2018 | | | | | |
| . | . | . | . | PHENYLEPHRINE W/TROPICAMIDE | | | | | | | |
| . | . | . | . | DILATION | | | | | | | |
| . | . | . | . | XYLONEST | | 18DEC2018 | | 1 | ml | ONCE | OCULAR |
| . | . | . | . | NERVOUS SYSTEM | | 18DEC2018 | | | | | |
| . | . | . | . | PRILOCAINE | | | | | | | |
| . | . | . | . | ANESTHESIA | | | | | | | |

Listing 16 (62 of 64): Concomitant treatments

Listing 16 (63 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|---|---------------------------------|-------------------------|---------|------|---------------|-----------------|-------|
| | | | | Sex | | | | | | | |
| 200203 | GEL | Male | 66 | BISOPROLOL | CARDIOVASCULAR SYSTEM | MAY2017 | YES | 2.5 | mg | DAILY | ORAL |
| . | . | . | . | BISOPROLOL | ARTERIAL HYPERTENSION | | | | | | |
| . | . | . | . | MYDRUM (TROPICAMIDE) | SENSORY ORGANS | 26JUN2018 | unknown | drop | UNKNOWN | OCULAR | |
| . | . | . | . | TROPICAMIDE | | 26JUN2018 | | | | | |
| . | . | . | . | MYDRIATIC DRUG FOR PREPARATION | | | | | | | |
| . | . | . | . | COSOPT S | SENSORY ORGANS | 26JUN2018 | unknown | drop | TWICE PER DAY | OCULAR | |
| . | . | . | . | SENSORY ORGANS | | 27JUN2018 | | | | | |
| . | . | . | . | COSOPT | | | | | | | |
| . | . | . | . | HIGH INTRAOCULAR PRESSURE (POSTOPERATIVE) | | | | | | | |
| . | . | . | . | BISOPROLOL | CARDIOVASCULAR SYSTEM | 23AUG2018 | 5 | mg | ONCE | ORAL | |
| . | . | . | . | BISOPROLOL | | 23AUG2018 | | | | | |
| . | . | . | . | NAUSEA/INCREASE OF BLOOD PRESSURE | | | | | | | |
| . | . | . | . | PANTOZOL | ALIMENTARY TRACT AND METABOLISM | 23AUG2018 | 40 | mg | ONCE | ORAL | |
| . | . | . | . | PANTOPRAZOLE | | 23AUG2018 | | | | | |
| . | . | . | . | HEARTBURN | | | | | | | |
| . | . | . | . | METOCLOPRAMID | ALIMENTARY TRACT AND METABOLISM | 3SEP2018 | YES | 20 | drop | 3 TIMES PER DAY | ORAL |
| . | . | . | . | METOCLOPRAMIDE | | | | | | | |
| . | . | . | . | HEARTBURN | | | | | | | |
| . | . | . | . | BISOPROLOL | CARDIOVASCULAR SYSTEM | 25AUG2018 | 5 | mg | ONCE | ORAL | |
| . | . | . | . | BISOPROLOL | | 25AUG2018 | | | | | |
| . | . | . | . | NAUSEA/INCREASE OF BLOOD PRESSURE | | | | | | | |

Listing 16 (64 of 64): Concomitant treatments

| Sbj Code | Study drug | Age (year) | Preferred term/ Indication | Reported term/ Therapeutic area/ | | Start date/ End date | Ongoing | Dose | Units | Freq. | Route |
|-------------|---------------|---------------|-------------------------------|--|-------------------------|-------------------------|---------|------|-------|---------|--------|
| | | | | Sex | | | | | | | |
| 200204 | GEL | Male | 58 | HYGROTON (CHLORTALIDON) | CARDIOVASCULAR SYSTEM | 2008 | YES | 25 | mg | DAILY | ORAL |
| . | . | . | . | CHLORTALIDONE | | | | | | | |
| . | . | . | . | HYPERTENSION | | | | | | | |
| . | . | . | . | ALLOPURINOL (ALLOPURINOL) | MUSCULO-SKELETAL SYSTEM | 2008 | YES | 150 | mg | DAILY | ORAL |
| . | . | . | . | ALLOPURINOL | | | | | | | |
| . | . | . | . | HYPERURICEMIA | | | | | | | |
| . | . | . | . | MYDRUM (TROPICAMIDE) | SENSORY ORGANS | 3JUL2018 | | 5 | mg/ml | UNKNOWN | OCULAR |
| . | . | . | . | TROPICAMIDE | | 3JUL2018 | | | | | |
| . | . | . | . | MYDRIATIC DRUG FOR OPERATION PREPARATION | | | | | | | |

SAS program: L03_List_16.sas - SAS dataset name(s): RAND,DEMOGRAPHY,CMED_COD

Listing 17 (1 of 6): Adverse events

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| Sbj code | Study drug | Age Sex | Reported term: | System Organ Class: | Preferred term : | Start date: | End date: | SAE: | Severity: | Study drug relat.: | Action taken with study drug: | Other action taken: | Suspension of study drug: | Outcome: |
|----------|------------|-----------|--|-------------------------|---------------------------|-------------|-----------|------|-----------|--------------------|-------------------------------|---------------------|---|---------------------|
| 100103 | | Female 70 | IPERSENSIBILITY TO PRE-OPERATIVE BROMFENAC | Immune system disorders | Drug hypersensitivity | | | NO | MILD | UNRELATED | NONE | OTHER | | COMpletely RECOVERY |
| 100313 | GEL | Male 71 | BREAKAGE POSTERIORE CAPSULE | Eye disorders | Posterior capsule rupture | | | NO | Moderate | UNRELATED | PRODUCT WITHDRAWN | CONCOMITANT THERAPY | OTHER THERAPY (DIAMOX AND VIGAMOX) | COMpletely RECOVERY |
| 100337 | GEL | Male 72 | BREAKAGE OF THE POSTERIOR CAPSULE | Eye disorders | Posterior capsule rupture | | | NO | MILD | UNRELATED | NONE | OTHER | THE PAZ DECIDES NOT TO CONTINUE THE STUDY | COMpletely RECOVERY |

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Listing 17 (2 of 6): Adverse events

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| Sbj code | Study drug | Age Sex | (year) |
|----------|------------|---------|--------|
| | | | |

Preferred term : Intraocular pressure increased

Start date: 17JAN2018
End date: 18JAN2018
SAE: NO
Severity: MILD
Study drug relat.: UNRELATED
Action taken with study drug: NONE
Other action taken: CONCOMITANT THERAPY
Outcome: COMPLETELY RECOVERY

200103 DROP Male 82 Reported term: FOREIGN BODY FEELING IN THE LEFT EYE
System Organ Class: Eye disorders
Preferred term : Foreign body sensation in eyes

Start date: 14MAR2018
End date: 28MAR2018
SAE: NO
Severity: MILD
Study drug relat.: UNRELATED
Action taken with study drug: NONE
Other action taken: CONCOMITANT THERAPY
TEAR SUBSTITUTE GIVEN
Outcome: COMPLETELY RECOVERY

200103 DROP Male 82 Reported term: MAKULA EDEMA IN THE RIGHT EYE
System Organ Class: Eye disorders
Preferred term : Macular oedema

Start date: 28MAR2018
End date: 16APR2018
SAE: YES
Severity: MILD
Study drug relat.: UNRELATED
Action taken with study drug: NONE
Other action taken: CONCOMITANT THERAPY
NEVANAC GIVEN
Outcome: COMPLETELY RECOVERY

Listing 17 (3 of 6): Adverse events

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| Sbj code | Study drug | Age Sex | Reported term: | System Organ Class: | Preferred term : |
|----------|------------|-----------|---|--|-----------------------|
| 200107 | DROP | Female 54 | ALLERGICAL REACTION ON STUDY MEDICATION | Immune system disorders | Drug hypersensitivity |
| | | | | | |
| | | | Start date: 03JUL2018 | | |
| | | | End date: 05JUL2018 | | |
| | | | SAE: NO | | |
| | | | Severity: MODERATE | | |
| | | | Study drug relat.: POSSIBLY | | |
| | | | Action taken with study drug: PRODUCT WITHDRAWAN | | |
| | | | Other action taken: OTHER | | |
| | | | DEXAPOS AND DEXAGEL PRESCRIBED | | |
| | | | Outcome: COMPLETELY RECOVERY | | |
| ----- | ----- | ----- | ----- | ----- | ----- |
| 200109 | GEL | Female 84 | IRRITATION WITH FIBRIN REACTION | | |
| | | | System Organ Class: | Injury, poisoning and procedural complications | |
| | | | Preferred term : | Fibrin deposition on lens postoperative | |
| | | | Start date: 03OCT2018 | | |
| | | | End date: 10OCT2018 | | |
| | | | SAE: NO | | |
| | | | Severity: MODERATE | | |
| | | | Study drug relat.: UNLIKELY | | |
| | | | Action taken with study drug: PRODUCT WITHDRAWAN | | |
| | | | Other action taken: OTHER | | |
| | | | LOCAL CORTICOSTEROID GIVEN, HOURLY | | |
| | | | Outcome: COMPLETELY RECOVERY | | |
| ----- | ----- | ----- | ----- | ----- | ----- |
| 200110 | DROP | Male 64 | VASCULAR OCCLUSION | | |
| | | | System Organ Class: | Vascular disorders | |
| | | | Preferred term : | Vascular occlusion | |
| | | | Start date: 17OCT2018 | | |
| | | | End date: 09DEC2018 | | |
| | | | SAE: YES | | |
| | | | Severity: SEVERE | | |
| | | | Study drug relat.: UNRELATED | | |
| | | | Action taken with study drug: NONE | | |
| | | | Other action taken: OTHER | | |
| | | | PLANNED HOSPITALISATION FOR DIAGNOSTICS FOT THE 19-OCT-2018, PREDNIPOS PRESCRIBED | | |
| | | | Outcome: COMPLETELY RECOVERY | | |

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Listing 17 (4 of 6): Adverse events

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| Sbj code | Study drug | Age Sex | Reported term: | System Organ Class: | Action taken with study drug: | Other action taken: | Start date: | End date: | SAE: | Severity: | Study drug relat.: | Outcome: |
|----------|------------|---------|-------------------------------------|---------------------|-------------------------------|--|-------------|-----------|------|-----------|--------------------|---------------------|
| 200111 | GEL | Male 73 | FOREIGN BODY SENSATION | Eye disorders | NONE | CONCOMITANT THERAPY CORNEREGEL PRN | 06NOV2018 | 07NOV2018 | NO | MODERATE | UNRELATED | COMPLETELY RECOVERY |
| 200111 | GEL | Male 73 | INCREASED IOP | Investigations | NONE | CONCOMITANT THERAPY ADDITIONAL EYE DROPS TO LOWER DOWN THE IOP | 06NOV2018 | 07NOV2018 | NO | MODERATE | UNRELATED | COMPLETELY RECOVERY |
| 200112 | DROP | Male 85 | PAINFULL BODY SENSATION IN LEFT EYE | Eye disorders | NONE | CONCOMITANT THERAPY HYLO PARIN EYE DROPS | 30NOV2018 | 05DEC2018 | NO | MILD | UNRELATED | COMPLETELY RECOVERY |

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Listing 17 (5 of 6): Adverse events

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| Sbj code | Study drug | Age Sex | Reported term: | System Organ Class: | Preferred term : | Start date: | End date: | SAE: | Severity: | Study drug relat.: | Action taken with study drug: | Other action taken: | Outcome: |
|----------|------------|-----------|---|-----------------------------|--------------------------------|-------------|-----------|------|-----------|--------------------|-------------------------------|--|---------------------|
| 200113 | DROP | Male 77 | HORDEOLUM | Infections and infestations | Hordeolum | 21NOV2018 | 28DEC2018 | NO | MILD | UNRELATED | NONE | CONCOMITANT THERAPY FLOXAL 3 TIMES PER DA | COMPLETELY RECOVERY |
| 200202 | DROP | Female 71 | CONJUNCTIVA HYPEREMIA | Eye disorders | Conjunctival hyperaemia | 06JUL2018 | . | NO | MILD | UNLIKELY | NONE | CONCOMITANT THERAPY DICLOFENAC EYEDROPS | PERSISTENT |
| 200203 | GEL | Male 66 | HIGH INTRAOCULAR PRESSURE (POSTOPERATIVE) | Investigations | Intraocular pressure increased | 26JUN2018 | 27JUN2018 | NO | MILD | UNLIKELY | NONE | CONCOMITANT THERAPY TOPICAL ADMINISTRATTION OF COSOPT D GTT | COMPLETELY RECOVERY |

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Listing 17 (6 of 6): Adverse events

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| Sbj code | Study drug | Age Sex | Reported term: | System Organ Class: | Preferred term : | Start date: | End date: | SAE: | Severity: | Study drug relat.: | Action taken with study drug: | Other action taken: | Outcome: |
|----------|------------|---------|----------------------------|----------------------------|--------------------------|-------------|-----------|------|-----------|--------------------|-------------------------------|---------------------|---------------------|
| 200203 | GEL | Male 66 | NAUSEA | Gastrointestinal disorders | Nausea | 23AUG2018 | 25AUG2018 | NO | MILD | UNLIKELY | NONE | CONCOMITANT THERAPY | COMPLETELY RECOVERY |
| 200203 | GEL | Male 66 | INCREASE OF BLOOD PRESSURE | Investigations | Blood pressure increased | 23AUG2018 | 25AUG2018 | NO | MILD | UNLIKELY | NONE | CONCOMITANT THERAPY | COMPLETELY RECOVERY |
| 200203 | GEL | Male 66 | HEARTBURN | Gastrointestinal disorders | Dyspepsia | 23AUG2018 | . | NO | MODERATE | UNLIKELY | NONE | CONCOMITANT THERAPY | PERSISTENT |

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SAS program: L03_List_17.sas - SAS dataset name(s): RAND,DEMOGRAPHY,AE_COD

Listing 18 (1 of 1): Unscheduled visit

| Sbj | Study | Age | Adverse | Concomitant | | | |
|--------|-------|--------|---------|-------------|------------|-------|------------------------|
| Code | drug | Sex | (year) | event | medication | Other | If OTHER, specify |
| 100302 | GEL | Male | 61 | . | . | Yes | STINGING |
| 100335 | DROP | Female | 80 | . | . | Yes | CLINICAL DECISION |
| 100354 | GEL | Female | 80 | . | . | Yes | CONJUNCTIVAL HYPEREMIA |
| 200101 | GEL | Female | 66 | Yes | Yes | . | |
| 200103 | DROP | Male | 82 | Yes | . | Yes | TEAR SUBSTITUTE |
| 200111 | GEL | Male | 73 | Yes | Yes | Yes | FOREIGN BODY SENSATION |
| 200112 | DROP | Male | 85 | Yes | Yes | . | |
| 200202 | DROP | Female | 71 | Yes | Yes | . | |

SAS program: L03_List_18.sas - SAS dataset name(s): RAND,DEMOGRAPHY,UNS_REAS