



Clinical trial results:

A Phase 2b, Randomized, Double Blind, Vehicle Controlled, Parallel Group, Dose Ranging Study to Assess the Efficacy, Safety, Tolerability and Pharmacokinetics of PF-06700841 Cream Applied Once or Twice Daily for 6 Weeks in Participants With Mild or Moderate Atopic Dermatitis

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2018-003050-24 |
| Trial protocol | LV DE HU BG PL DK |
| Global end of trial date | 07 May 2020 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v2 (current) |
| This version publication date | 15 July 2021 |
| First version publication date | 12 November 2020 |
| Version creation reason | |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | B7931022 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03903822 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Pfizer Inc. |
| Sponsor organisation address | 235 E 42nd Street, New York, United States, NY 10017 |
| Public contact | Pfizer Inc., Pfizer ClinicalTrials.gov Call Center, 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact | Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|-------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 03 September 2020 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 07 May 2020 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy of multiple dose levels of PF-06700841 topical cream versus vehicle, applied once daily (QD) or twice daily (BID), on percent change from baseline in eczema area and severity Index (EASI) in subjects with mild or moderate atopic dermatitis (AD).

Protection of trial subjects:

The study was conducted in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------|
| Actual start date of recruitment | 13 May 2019 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | Australia: 27 |
| Country: Number of subjects enrolled | Bulgaria: 17 |
| Country: Number of subjects enrolled | Canada: 10 |
| Country: Number of subjects enrolled | Denmark: 1 |
| Country: Number of subjects enrolled | Germany: 28 |
| Country: Number of subjects enrolled | Hungary: 9 |
| Country: Number of subjects enrolled | Japan: 38 |
| Country: Number of subjects enrolled | Latvia: 10 |
| Country: Number of subjects enrolled | Poland: 11 |
| Country: Number of subjects enrolled | United States: 141 |
| Worldwide total number of subjects | 292 |
| EEA total number of subjects | 76 |

Notes:

Subjects enrolled per age group

| | |
|--|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 | 0 |

| | |
|--|-----|
| wk | |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 6 |
| Adults (18-64 years) | 261 |
| From 65 to 84 years | 25 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study was conducted at 77 sites in the 10 countries from 13 May 2019 to 07 May 2020. A total of 292 subjects were enrolled.

Period 1

| | |
|------------------------------|---------------------------|
| Period 1 title | Treatment Phase (6 Weeks) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator |

Arms

| | |
|------------------------------|-------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Vehicle Cream Once Daily (QD) |

Arm description:

Subjects or caregivers of subjects, topically applied vehicle cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |

Dosage and administration details:

Subject received vehicle cream once daily for maximum of 6 weeks.

| | |
|------------------|---------------------------|
| Arm title | PF-06700841 0.1% Cream QD |
|------------------|---------------------------|

Arm description:

Subjects or caregivers of subjects, topically applied of PF-06700841 0.1 percent (%) cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |

Dosage and administration details:

Subject received PF-06700841 0.1 % cream once daily for maximum of 6 weeks.

| | |
|------------------|---------------------------|
| Arm title | PF-06700841 0.3% Cream QD |
|------------------|---------------------------|

Arm description:

Subjects or caregivers of subjects, topically applied of PF-06700841 0.3 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|---|---------------------------------|
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |
| Dosage and administration details: | |
| Subject received PF-06700841 0.3 % cream once daily for maximum of 6 weeks. | |
| Arm title | PF-06700841 1.0% Cream QD |
| Arm description: | |
| Subjects or caregivers of subjects, topically applied of PF-06700841 1.0 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Arm type | Experimental |
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |
| Dosage and administration details: | |
| Subject received PF-06700841 1.0 % cream once daily for maximum of 6 weeks. | |
| Arm title | PF-06700841 3.0% Cream QD |
| Arm description: | |
| Subjects or caregivers of subjects, topically applied of PF-06700841 3.0 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Arm type | Experimental |
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |
| Dosage and administration details: | |
| Subject received PF-06700841 3.0% cream once daily for maximum of 6 weeks. | |
| Arm title | Vehicle Cream Twice Daily (BID) |
| Arm description: | |
| Subjects or caregivers of subjects, topically applied vehicle cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Arm type | Experimental |
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |
| Dosage and administration details: | |
| Subject received vehicle cream twice daily for maximum of 6 weeks. | |
| Arm title | PF-06700841 0.3% Cream BID |
| Arm description: | |
| Subjects or caregivers of subjects topically applied PF-06700841 0.3% cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Arm type | Experimental |

| | |
|---|----------------------------|
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |
| Dosage and administration details: | |
| Subject received PF-06700841 0.3% cream twice daily for maximum of 6 weeks. | |
| Arm title | PF-06700841 1.0% Cream BID |

Arm description:

Subjects or caregivers of subjects topically applied PF-06700841 1.0% cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |

Dosage and administration details:

Subject received PF-06700841 1.0 % cream twice daily for maximum of 6 weeks.

| Number of subjects in period 1 | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD |
|---------------------------------------|-------------------------------|---------------------------|---------------------------|
| Started | 37 | 37 | 36 |
| Completed | 28 | 27 | 33 |
| Not completed | 9 | 10 | 3 |
| Consent withdrawn by subject | 2 | 4 | 2 |
| Physician decision | - | 2 | - |
| Adverse event, non-fatal | 3 | 3 | 1 |
| Pregnancy | - | - | - |
| Unspecified | 2 | 1 | - |
| Refused Further Treatment | 2 | - | - |
| Lost to follow-up | - | - | - |
| Protocol deviation | - | - | - |
| Lack of efficacy | - | - | - |

| Number of subjects in period 1 | PF-06700841 1.0% Cream QD | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) |
|---------------------------------------|---------------------------|---------------------------|---------------------------------|
| Started | 37 | 36 | 36 |
| Completed | 32 | 31 | 25 |
| Not completed | 5 | 5 | 11 |
| Consent withdrawn by subject | 2 | 1 | 2 |
| Physician decision | - | - | - |
| Adverse event, non-fatal | 1 | 1 | 6 |
| Pregnancy | 1 | 1 | - |

| | | | |
|---------------------------|---|---|---|
| Unspecified | - | 1 | 1 |
| Refused Further Treatment | - | - | 1 |
| Lost to follow-up | - | - | - |
| Protocol deviation | 1 | - | - |
| Lack of efficacy | - | 1 | 1 |

| Number of subjects in period 1 | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|--------------------------------|----------------------------|----------------------------|
| Started | 36 | 37 |
| Completed | 31 | 33 |
| Not completed | 5 | 4 |
| Consent withdrawn by subject | 3 | 3 |
| Physician decision | - | - |
| Adverse event, non-fatal | 1 | - |
| Pregnancy | - | - |
| Unspecified | - | - |
| Refused Further Treatment | - | - |
| Lost to follow-up | 1 | 1 |
| Protocol deviation | - | - |
| Lack of efficacy | - | - |

Period 2

| | |
|------------------------------|---------------------------|
| Period 2 title | Follow up Phase (4 Weeks) |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator |

Arms

| | |
|------------------------------|-------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Vehicle Cream Once Daily (QD) |

Arm description:

Subjects or caregivers of subjects topically applied vehicle cream on all eligible atopic dermatitis (AD) areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |

Dosage and administration details:

Subject received vehicle cream once daily for maximum of 6 weeks.

| | |
|------------------|---------------------------|
| Arm title | PF-06700841 0.1% Cream QD |
|------------------|---------------------------|

Arm description:

Subjects or caregivers of subjects topically applied of PF-06700841 0.1 percent (%) cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |

Dosage and administration details:

Subject received PF-06700841 0.1 % cream once daily for maximum of 6 weeks.

| | |
|------------------|---------------------------|
| Arm title | PF-06700841 0.3% Cream QD |
|------------------|---------------------------|

Arm description:

Subjects or caregivers of subjects topically applied of PF-06700841 0.3 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |

Dosage and administration details:

Subject received PF-06700841 0.3 % cream once daily for maximum of 6 weeks.

| | |
|------------------|---------------------------|
| Arm title | PF-06700841 1.0% Cream QD |
|------------------|---------------------------|

Arm description:

Subjects or caregivers of subjects topically applied of PF-06700841 1.0 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |

Dosage and administration details:

Subject received PF-06700841 1.0 % cream once daily for maximum of 6 weeks.

| | |
|------------------|---------------------------|
| Arm title | PF-06700841 3.0% Cream QD |
|------------------|---------------------------|

Arm description:

Subjects or caregivers of subjects topically applied of PF-06700841 3.0 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |

Dosage and administration details:

Subject received PF-06700841 3.0 % cream once daily for maximum of 6 weeks.

| | |
|------------------|---------------------------------|
| Arm title | Vehicle Cream Twice Daily (BID) |
|------------------|---------------------------------|

Arm description:

Subjects or caregivers of subjects topically applied vehicle cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |

Dosage and administration details:

Subject received vehicle cream twice daily for maximum of 6 weeks.

| | |
|------------------|----------------------------|
| Arm title | PF-06700841 0.3% Cream BID |
|------------------|----------------------------|

Arm description:

Subjects or caregivers of subjects topically applied PF-06700841 0.3% cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |

Dosage and administration details:

Subject received PF-06700841 0.3% cream twice daily for maximum of 6 weeks.

| | |
|------------------|----------------------------|
| Arm title | PF-06700841 1.0% Cream BID |
|------------------|----------------------------|

Arm description:

Subjects or caregivers of subjects topically applied PF-06700841 1.0% cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | PF-06700841 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |

Dosage and administration details:

Subject received PF-06700841 1.0 % cream twice daily for maximum of 6 weeks.

| Number of subjects in period 2 | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD |
|---------------------------------------|--------------------------------------|----------------------------------|----------------------------------|
| Started | 28 | 27 | 33 |
| Completed | 29 | 29 | 32 |
| Not completed | 8 | 8 | 4 |
| Consent withdrawn by subject | 2 | 5 | 3 |
| Refused Further Study Procedures | - | - | - |
| Adverse event, non-fatal | 3 | 2 | 1 |
| Pregnancy | - | - | - |

| | | | |
|-----------------------|---|----|---|
| Unspecified | 1 | 1 | - |
| Lost to follow-up | 2 | - | - |
| Lack of efficacy | - | - | - |
| Joined | 9 | 10 | 3 |
| Continue to follow up | 9 | 10 | 3 |

| Number of subjects in period 2 | PF-06700841 1.0% Cream QD | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) |
|---------------------------------------|------------------------------|------------------------------|------------------------------------|
| Started | 32 | 31 | 25 |
| Completed | 33 | 32 | 28 |
| Not completed | 4 | 4 | 8 |
| Consent withdrawn by subject | 2 | 2 | 2 |
| Refused Further Study Procedures | - | - | 1 |
| Adverse event, non-fatal | 1 | - | 5 |
| Pregnancy | 1 | 1 | - |
| Unspecified | - | - | - |
| Lost to follow-up | - | - | - |
| Lack of efficacy | - | 1 | - |
| Joined | 5 | 5 | 11 |
| Continue to follow up | 5 | 5 | 11 |

| Number of subjects in period 2 | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|---------------------------------------|-------------------------------|-------------------------------|
| Started | 31 | 33 |
| Completed | 31 | 31 |
| Not completed | 5 | 6 |
| Consent withdrawn by subject | 3 | 3 |
| Refused Further Study Procedures | - | - |
| Adverse event, non-fatal | 1 | - |
| Pregnancy | - | - |
| Unspecified | - | - |
| Lost to follow-up | 1 | 3 |
| Lack of efficacy | - | - |
| Joined | 5 | 4 |
| Continue to follow up | 5 | 4 |

Baseline characteristics

Reporting groups

| | |
|---|---------------------------------|
| Reporting group title | Vehicle Cream Once Daily (QD) |
| Reporting group description: Subjects or caregivers of subjects, topically applied vehicle cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 0.1% Cream QD |
| Reporting group description: Subjects or caregivers of subjects, topically applied of PF-06700841 0.1 percent (%) cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 0.3% Cream QD |
| Reporting group description: Subjects or caregivers of subjects, topically applied of PF-06700841 0.3 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 1.0% Cream QD |
| Reporting group description: Subjects or caregivers of subjects, topically applied of PF-06700841 1.0 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 3.0% Cream QD |
| Reporting group description: Subjects or caregivers of subjects, topically applied of PF-06700841 3.0 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | Vehicle Cream Twice Daily (BID) |
| Reporting group description: Subjects or caregivers of subjects, topically applied vehicle cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 0.3% Cream BID |
| Reporting group description: Subjects or caregivers of subjects topically applied PF-06700841 0.3% cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 1.0% Cream BID |
| Reporting group description: Subjects or caregivers of subjects topically applied PF-06700841 1.0% cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |

| Reporting group values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD |
|--|-------------------------------|---------------------------|---------------------------|
| Number of subjects | 37 | 37 | 36 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |

| | | | |
|---|---------|---------|---------|
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 2 | 1 | 1 |
| Adults (18-64 years) | 31 | 32 | 31 |
| From 65-84 years | 4 | 4 | 4 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous | | | |
| Units: Years | | | |
| arithmetic mean | 39.1 | 40.8 | 43.4 |
| standard deviation | ± 16.80 | ± 15.35 | ± 16.43 |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| Female | 20 | 19 | 24 |
| Male | 17 | 18 | 12 |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 4 | 8 | 4 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 8 | 7 | 9 |
| White | 24 | 22 | 21 |
| More than one race | 0 | 0 | 2 |
| Unknown or Not Reported | 1 | 0 | 0 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 3 |
| Not Hispanic or Latino | 37 | 37 | 32 |
| Unknown or Not Reported | 0 | 0 | 1 |

| Reporting group values | PF-06700841 1.0% Cream QD | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) |
|---|------------------------------|------------------------------|------------------------------------|
| Number of subjects | 37 | 36 | 36 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 1 | 0 | 1 |
| Adults (18-64 years) | 36 | 34 | 29 |
| From 65-84 years | 0 | 2 | 6 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous | | | |
| Units: Years | | | |
| arithmetic mean | 38.4 | 40.5 | 42.3 |
| standard deviation | ± 12.90 | ± 12.30 | ± 18.18 |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| Female | 23 | 15 | 19 |
| Male | 14 | 21 | 17 |

| | | | |
|---|----|----|----|
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 8 | 10 | 9 |
| Native Hawaiian or Other Pacific Islander | 1 | 0 | 1 |
| Black or African American | 6 | 4 | 6 |
| White | 20 | 21 | 20 |
| More than one race | 2 | 1 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 2 | 1 | 3 |
| Not Hispanic or Latino | 35 | 35 | 33 |
| Unknown or Not Reported | 0 | 0 | 0 |

| Reporting group values | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID | Total |
|---|-------------------------------|-------------------------------|-------|
| Number of subjects | 36 | 37 | 292 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 6 |
| Adults (18-64 years) | 33 | 35 | 261 |
| From 65-84 years | 3 | 2 | 25 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous | | | |
| Units: Years | | | |
| arithmetic mean | 39.4 | 38.1 | |
| standard deviation | ± 17.27 | ± 15.34 | - |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| Female | 16 | 20 | 156 |
| Male | 20 | 17 | 136 |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 9 | 7 | 59 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 2 |
| Black or African American | 5 | 6 | 51 |
| White | 22 | 24 | 174 |
| More than one race | 0 | 0 | 5 |
| Unknown or Not Reported | 0 | 0 | 1 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 4 | 13 |

| | | | |
|-------------------------|----|----|-----|
| Not Hispanic or Latino | 35 | 33 | 277 |
| Unknown or Not Reported | 1 | 0 | 2 |

End points

End points reporting groups

| | |
|---|---------------------------------|
| Reporting group title | Vehicle Cream Once Daily (QD) |
| Reporting group description: Subjects or caregivers of subjects, topically applied vehicle cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 0.1% Cream QD |
| Reporting group description: Subjects or caregivers of subjects, topically applied of PF-06700841 0.1 percent (%) cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 0.3% Cream QD |
| Reporting group description: Subjects or caregivers of subjects, topically applied of PF-06700841 0.3 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 1.0% Cream QD |
| Reporting group description: Subjects or caregivers of subjects, topically applied of PF-06700841 1.0 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 3.0% Cream QD |
| Reporting group description: Subjects or caregivers of subjects, topically applied of PF-06700841 3.0 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | Vehicle Cream Twice Daily (BID) |
| Reporting group description: Subjects or caregivers of subjects, topically applied vehicle cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 0.3% Cream BID |
| Reporting group description: Subjects or caregivers of subjects topically applied PF-06700841 0.3% cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 1.0% Cream BID |
| Reporting group description: Subjects or caregivers of subjects topically applied PF-06700841 1.0% cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | Vehicle Cream Once Daily (QD) |
| Reporting group description: Subjects or caregivers of subjects topically applied vehicle cream on all eligible atopic dermatitis (AD) areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 0.1% Cream QD |
| Reporting group description: Subjects or caregivers of subjects topically applied of PF-06700841 0.1 percent (%) cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 0.3% Cream QD |
| Reporting group description: Subjects or caregivers of subjects topically applied of PF-06700841 0.3 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined | |

on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|--|---------------------------------|
| Reporting group title | PF-06700841 1.0% Cream QD |
| Reporting group description: | |
| Subjects or caregivers of subjects topically applied of PF-06700841 1.0 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 3.0% Cream QD |
| Reporting group description: | |
| Subjects or caregivers of subjects topically applied of PF-06700841 3.0 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | Vehicle Cream Twice Daily (BID) |
| Reporting group description: | |
| Subjects or caregivers of subjects topically applied vehicle cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 0.3% Cream BID |
| Reporting group description: | |
| Subjects or caregivers of subjects topically applied PF-06700841 0.3% cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |
| Reporting group title | PF-06700841 1.0% Cream BID |
| Reporting group description: | |
| Subjects or caregivers of subjects topically applied PF-06700841 1.0% cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose. | |

Primary: Percent Change From Baseline in Eczema Area and Severity Index (EASI) Total Score at Week 6: Multiple Imputation

| | |
|--|--|
| End point title | Percent Change From Baseline in Eczema Area and Severity Index (EASI) Total Score at Week 6: Multiple Imputation |
| End point description: | |
| EASI:severity of subject's AD based on severity of AD clinical signs and % of body surface area (BSA) affected. Severity of clinical signs of AD scored separately for each of 4 body regions on4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score was based upon % BSA with AD in each 4 body region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score =0.1*Ah*(Eh+Ih+Exh+Lh) + 0.2*Au*(Eu+Iu+ExU+Lu) + 0.3*At*(Et+It+Ext+Lt) + 0.4*Al*(El+Il+Exl+LI); A = EASI area score; E = erythema; I = induration/papulation; Ex = excoriation; L = lichenification; h = head and neck; u = upper limbs; t = trunk; l = lower limbs. Total EASI score ranged from 0.0 to 72.0, higher scores = greater severity of AD. FAS:all subjects who were randomly assigned to study drug and applied at least 1 dose of study drug. Missing data were imputed with multiple imputation method based on reason for missing data. | |
| End point type | Primary |
| End point timeframe: | |
| Baseline, Week 6 | |

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|--|-------------------------------|---------------------------|---------------------------|---------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 37 | 36 | 37 |
| Units: Percent change | | | | |
| least squares mean (confidence interval 90%) | -44.4 (-57.3 to -31.6) | -58.3 (-71.2 to -45.5) | -64.6 (-77.1 to -52.1) | -70.1 (-82.1 to -58.0) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|--|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 36 | 36 | 36 | 37 |
| Units: Percent change | | | | |
| least squares mean (confidence interval 90%) | -67.9 (-80.6 to -55.3) | -47.6 (-57.5 to -37.7) | -58.6 (-67.5 to -49.7) | -75.0 (-83.8 to -66.2) |

Statistical analyses

| Statistical analysis title | Vehicle versus (vs) PF-06700841 0.1% Cream QD |
|---|---|
| Statistical analysis description: Analysis of covariance (ANCOVA) contained fixed factors of treatment and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.104 |
| Method | ANCOVA |
| Parameter estimate | Least square (LS) mean difference |
| Point estimate | -13.9 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -32.1 |
| upper limit | 4.3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 11.04 |

| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
|--|---|
| Statistical analysis description: ANCOVA contained fixed factors of treatment and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0334 |
| Method | ANCOVA |
| Parameter estimate | LS Mean Difference |
| Point estimate | -20.2 |

| | |
|----------------------|----------------------------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -38.3 |
| upper limit | -2.1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 11 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: ANCOVA contained fixed factors of treatment and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0086 |
| Method | ANCOVA |
| Parameter estimate | LS Mean Difference |
| Point estimate | -25.6 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -43.3 |
| upper limit | -8 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 10.75 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
| Statistical analysis description: ANCOVA contained fixed factors of treatment and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0158 |
| Method | ANCOVA |
| Parameter estimate | LS Mean Difference |
| Point estimate | -23.5 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -41.5 |
| upper limit | -5.5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 10.93 |

| | |
|--|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
| Statistical analysis description: ANCOVA contained fixed factors of treatment and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 72 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0879 |
| Method | ANCOVA |
| Parameter estimate | LS Mean Difference |
| Point estimate | -11 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -24.3 |
| upper limit | 2.4 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 8.11 |

| | |
|--|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
| Statistical analysis description: ANCOVA contained fixed factors of treatment and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0004 |
| Method | ANCOVA |
| Parameter estimate | LS Mean Difference |
| Point estimate | -27.4 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -40.7 |
| upper limit | -14.1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 8.11 |

| | |
|---|--|
| Secondary: Percentage of Subjects Achieving Investigator's Global Assessment (IGA) Score Clear (0) or Almost Clear (1) and a Reduction From Baseline of Greater Than or Equal to (≥ 2) Points at Week 6: Non-responder Imputation | |
| End point title | Percentage of Subjects Achieving Investigator's Global |

End point description:

IGA assesses severity of subject's AD on 5 point scale. 0= clear, no inflammatory signs of AD; 1= almost clear, AD not fully cleared-light pink residual lesions (except post-inflammatory hyperpigmentation), just perceptible erythema, papulation/induration lichenification, excoriation, and no oozing/crusting; 2=mild AD with light red lesions, slight but definite erythema, papulation/induration, lichenification, excoriation and no oozing/crusting; 3= moderate AD with red lesions, moderate erythema, papulation/induration, lichenification, excoriation and slight oozing/crusting and 4= severe AD with deep dark red lesions, severe erythema, papulation/induration, lichenification, excoriation and moderate to severe oozing/crusting. Higher scores indicating more severity of AD. Assessment excluded soles, palms and scalp. Full analysis set (FAS) was analyzed. Non-Responder Imputation (NRI) method: subjects with missing values were considered to be non-responders.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 6 | |

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|----------------------------------|-------------------------------|---------------------------|---------------------------|---------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 37 | 36 | 37 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 90%) | 10.8 (4.8 to 22.2) | 29.7 (18.5 to 43.3) | 33.3 (21.3 to 47.0) | 40.5 (28.0 to 54.4) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|----------------------------------|---------------------------|---------------------------------|----------------------------|----------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 36 | 36 | 36 | 37 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 90%) | 44.4 (30.2 to 59.1) | 13.9 (6.9 to 25.4) | 33.3 (21.3 to 47.0) | 27.0 (15.5 to 40.2) |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
| Statistical analysis description: | |
| Risk difference = difference in percentage of subjects. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |

| | |
|---|-----------------------------|
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0244 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 18.9 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 2.4 |
| upper limit | 34.7 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: | |
| Risk difference = difference in percentage of subjects. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0113 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 22.5 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 4.8 |
| upper limit | 38.6 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: | |
| Risk difference = difference in percentage of subjects. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0018 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 29.7 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 11 |
| upper limit | 45.7 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0007 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 33.6 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 13.7 |
| upper limit | 49.9 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

Risk difference = difference in percentage of subjects.

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 72 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0289 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 19.4 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 1.8 |
| upper limit | 36.5 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

Risk difference = difference in percentage of subjects.

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1145 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 13.1 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -2.9 |
| upper limit | 29.6 |

Secondary: Change From Baseline in Eczema Area and Severity Index (EASI) Total Score at Week 6: Multiple Imputation

| | |
|------------------------|--|
| End point title | Change From Baseline in Eczema Area and Severity Index (EASI) Total Score at Week 6: Multiple Imputation |
| End point description: | EASI:severity of subject's AD based on severity of AD clinical signs and % of BSA affected. Severity of clinical signs of AD scored separately for each of 4 body regions on4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score was based upon % BSA with AD in each 4 body region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score =0.1*Ah*(Eh+Ih+Exh+Lh) + 0.2*Au*(Eu+Iu+ExU+Lu) + 0.3*At*(Et+It+Ext+Lt) + 0.4*Al*(El+Il+Exl+Ll); A = EASI area score; E = erythema; I = induration/papulation; Ex = excoriation; L = lichenification; h = head and neck; u = upper limbs; t = trunk; l = lower limbs. Total EASI score ranged from 0.0 to 72.0, higher scores = greater severity of AD. FAS:all subjects who were randomly assigned to study drug and applied at least 1 dose of study drug. Missing data were imputed with multiple imputation method based on reason for missing data. |
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 6 | |

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|--|-------------------------------|---------------------------|---------------------------|---------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 37 | 36 | 37 |
| Units: Units on a scale | | | | |
| least squares mean (confidence interval 90%) | -3.2 (-4.1 to -2.3) | -4.5 (-5.4 to -3.6) | -4.6 (-5.5 to -3.7) | -4.8 (-5.7 to -3.9) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|------------------|---------------------------|---------------------------------|----------------------------|----------------------------|
|------------------|---------------------------|---------------------------------|----------------------------|----------------------------|

| | | | | |
|--|---------------------|---------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 36 | 36 | 36 | 37 |
| Units: Units on a scale | | | | |
| least squares mean (confidence interval 90%) | -5.5 (-6.4 to -4.7) | -3.6 (-4.3 to -3.0) | -4.4 (-5.0 to -3.8) | -5.3 (-5.9 to -4.7) |

Statistical analyses

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
| Statistical analysis description: ANCOVA contained fixed factors of treatment and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0488 |
| Method | ANCOVA |
| Parameter estimate | LS mean difference |
| Point estimate | -1.31 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -2.61 |
| upper limit | -0.01 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.79 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: ANCOVA contained fixed factors of treatment and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0413 |
| Method | ANCOVA |
| Parameter estimate | LS Mean Difference |
| Point estimate | -1.37 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -2.66 |
| upper limit | -0.07 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.788 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: ANCOVA contained fixed factors of treatment and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.02 |
| Method | ANCOVA |
| Parameter estimate | LS Mean Difference |
| Point estimate | -1.59 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -2.86 |
| upper limit | -0.32 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.773 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
| Statistical analysis description: ANCOVA contained fixed factors of treatment and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0011 |
| Method | ANCOVA |
| Parameter estimate | LS Mean Difference |
| Point estimate | -2.33 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -3.58 |
| upper limit | -1.08 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.758 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
| Statistical analysis description: ANCOVA contained fixed factors of treatment and baseline value. | |

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 72 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0727 |
| Method | ANCOVA |
| Parameter estimate | LS Mean Difference |
| Point estimate | -0.78 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -1.66 |
| upper limit | 0.1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.535 |

| | |
|--|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
| Statistical analysis description: ANCOVA contained fixed factors of treatment and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.001 |
| Method | ANCOVA |
| Parameter estimate | LS Mean Difference |
| Point estimate | -1.64 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -2.52 |
| upper limit | -0.77 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.534 |

Secondary: Percentage of Subjects Achieving ≥ 2 Points Reduction in Peak Pruritus Numerical Rating Scale (PP-NRS) From Baseline at Weeks 1, 2, 3, 4 and 6: Non-responder Imputation

| | |
|-----------------|---|
| End point title | Percentage of Subjects Achieving ≥ 2 Points Reduction in Peak Pruritus Numerical Rating Scale (PP-NRS) From Baseline at Weeks 1, 2, 3, 4 and 6: Non-responder Imputation |
|-----------------|---|

End point description:

The severity of itch (pruritus) due to AD was assessed using a horizontal NRS. Subjects at specified time points were asked the following question: "How would you rate your itch due to AD at the worst moment during the previous 24 hours?" The scale ranged from 0-10, where 0= no itch and 10= worst itch imaginable. Higher scores indicated worse itch. Full analysis set (FAS) included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "number of

subjects analysed (N)" signifies number of subjects evaluable for this end point. NRI method: subjects with missing values were considered to be non-responders.

| | |
|---------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 1, 2, 3, 4 and 6 | |

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|----------------------------------|-------------------------------|---------------------------|---------------------------|---------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 36 | 35 | 37 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 90%) | | | | |
| At Week 1 | 16.2 (7.3 to 29.3) | 16.7 (7.5 to 30.2) | 20.0 (11.0 to 33.8) | 29.7 (18.5 to 43.3) |
| At Week 2 | 24.3 (14.5 to 37.0) | 30.6 (18.9 to 44.0) | 42.9 (30.0 to 58.1) | 48.6 (34.3 to 63.0) |
| At Week 3 | 21.6 (11.2 to 34.3) | 38.9 (25.4 to 53.0) | 48.6 (33.8 to 63.5) | 59.5 (45.6 to 72.0) |
| At Week 4 | 35.1 (22.2 to 49.3) | 38.9 (25.4 to 53.0) | 51.4 (36.5 to 66.2) | 62.2 (48.0 to 75.2) |
| At Week 6 | 40.5 (28.0 to 54.4) | 41.7 (29.0 to 56.0) | 51.4 (36.5 to 66.2) | 56.8 (43.2 to 70.7) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|----------------------------------|---------------------------|---------------------------------|----------------------------|----------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 36 | 36 | 35 | 35 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 90%) | | | | |
| At Week 1 | 44.4 (30.2 to 59.1) | 13.9 (6.9 to 25.4) | 28.6 (16.4 to 41.9) | 25.7 (15.4 to 39.2) |
| At Week 2 | 61.1 (47.0 to 74.6) | 25.0 (14.9 to 38.0) | 45.7 (31.7 to 60.8) | 37.1 (23.6 to 52.2) |
| At Week 3 | 58.3 (44.0 to 71.0) | 33.3 (21.3 to 47.0) | 51.4 (36.5 to 66.2) | 57.1 (41.9 to 70.0) |
| At Week 4 | 58.3 (44.0 to 71.0) | 30.6 (18.9 to 44.0) | 60.0 (44.8 to 74.0) | 60.0 (44.8 to 74.0) |
| At Week 6 | 61.1 (47.0 to 74.6) | 30.6 (18.9 to 44.0) | 60.0 (44.8 to 74.0) | 60.0 (44.8 to 74.0) |

Statistical analyses

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
| Statistical analysis description: | |
| At Week 1: Risk difference = difference in percentage of subjects. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |

| | |
|---|-----------------------------|
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.5246 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 0.5 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -14.7 |
| upper limit | 16.4 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: | |
| At Week 1: Risk difference = difference in percentage of subjects. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 72 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.3906 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 3.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -12.5 |
| upper limit | 19.9 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: | |
| At Week 1: Risk difference = difference in percentage of subjects. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1193 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 13.5 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -3.2 |
| upper limit | 30.6 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 1: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0048 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 28.2 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 8.8 |
| upper limit | 45.5 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

At Week 1: Risk difference = difference in percentage of subjects.

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 71 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1245 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 11.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -4.3 |
| upper limit | 28 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

At Week 1: Risk difference = difference in percentage of subjects.

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 71 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0777 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 14.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -2 |
| upper limit | 31.1 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 0.1% Cream QD

Statistical analysis description:

At Week 2: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.3322 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 6.2 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -12.2 |
| upper limit | 24.4 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 0.3% Cream QD

Statistical analysis description:

At Week 2: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 72 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0535 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 18.5 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -0.3 |
| upper limit | 36.5 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 2: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0159 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 24.3 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 4.5 |
| upper limit | 41.9 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 2: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0008 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 36.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 15.4 |
| upper limit | 54 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

At Week 2: Risk difference = difference in percentage of subjects.

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 71 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0386 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 20.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 1.5 |
| upper limit | 38.8 |

Statistical analysis title

Vehicle Cream BID vs PF-06700841 1.0% Cream BID

Statistical analysis description:

At Week 2: Risk difference = difference in percentage of subjects.

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 71 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1485 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 12.1 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -6.4 |
| upper limit | 30.3 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 0.1% Cream QD

Statistical analysis description:

At Week 3: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.062 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 17.3 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -0.8 |
| upper limit | 34.8 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 3: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 72 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0089 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 26.9 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 6.5 |
| upper limit | 44.4 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 3: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0005 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 37.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 17.5 |
| upper limit | 54.7 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 3: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0007 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 36.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 15.4 |
| upper limit | 54 |

Statistical analysis title

Vehicle Cream BID vs PF-06700841 0.3% Cream BID

Statistical analysis description:

At Week 3: Risk difference = difference in percentage of subjects.

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 71 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0711 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 18.1 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -2 |
| upper limit | 37.5 |

Statistical analysis title

Vehicle Cream BID vs PF-06700841 1.0% Cream BID

Statistical analysis description:

At Week 3: Risk difference = difference in percentage of subjects.

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 71 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0266 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 23.8 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 2.7 |
| upper limit | 42.5 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At week 4: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.4173 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 3.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -15.3 |
| upper limit | 23.1 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 4: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 72 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1096 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 16.3 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -4.3 |
| upper limit | 35.6 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 4: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0133 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 27 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 6.1 |
| upper limit | 45.7 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 3.0% Cream QD

Statistical analysis description:

At Week 4: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0304 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 23.2 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 2.6 |
| upper limit | 41.7 |

Statistical analysis title

Vehicle Cream BID vs PF-06700841 0.3% Cream BID

Statistical analysis description:

At Week 4: Risk difference = difference in percentage of subjects.

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 71 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0078 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 29.4 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 7.2 |
| upper limit | 47.6 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

At Week 4: Risk difference = difference in percentage of subjects.

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 71 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0078 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 29.4 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 7.2 |
| upper limit | 47.6 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 6: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.4966 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -18.4 |
| upper limit | 20.4 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 6: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 72 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.2753 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 10.9 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -9.3 |
| upper limit | 30.1 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 1.0% Cream QD

Statistical analysis description:

At Week 6: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1036 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 16.2 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -4.2 |
| upper limit | 35.7 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 3.0% Cream QD

Statistical analysis description:

At Week 6: Risk difference = difference in percentage of subjects.

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0457 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 20.6 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 39.6 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

At Week 6: Risk difference = difference in percentage of subjects.

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 71 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0078 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 29.4 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 7.2 |
| upper limit | 47.6 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

At Week 6: Risk difference = difference in percentage of subjects.

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 71 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0078 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 29.4 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 7.2 |
| upper limit | 47.6 |

Secondary: Percentage of Subjects Achieving ≥ 4 Points Reduction in Peak Pruritus Numerical Rating Scale (PP-NRS) From Baseline at Weeks 1, 2, 3, 4, 6 and Follow-up Visit: Non-responder Imputation

| | |
|--|--|
| End point title | Percentage of Subjects Achieving ≥ 4 Points Reduction in Peak Pruritus Numerical Rating Scale (PP-NRS) From Baseline at Weeks 1, 2, 3, 4, 6 and Follow-up Visit: Non-responder Imputation |
| End point description: | |
| The severity of itch (pruritus) due to AD was assessed using a horizontal NRS. Subjects at specified time points were asked the following question: "How would you rate your itch due to AD at the worst moment during the previous 24 hours?" The scale ranged from 0-10, where 0= no itch and 10= worst itch imaginable. Higher scores indicated worse itch. Full analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "number of subjects analysed" signifies number of subjects evaluable for this end point. NRI method: subjects with missing values were considered to be non-responders. | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 1, 2, 3, 4, 6 and follow up visit (28 days after last dose of study drug = maximum up to Day 71) | |

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|----------------------------------|-------------------------------|---------------------------|---------------------------|---------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 33 | 30 | 32 | 31 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 90%) | | | | |
| At Week 1 | 0.0 (0.0 to 8.2) | 3.3 (0.4 to 14.0) | 3.1 (0.3 to 13.1) | 16.1 (8.1 to 29.7) |
| At Week 2 | 9.1 (3.4 to 20.2) | 10.0 (3.7 to 22.1) | 9.4 (3.5 to 20.7) | 19.4 (8.8 to 32.7) |
| At Week 3 | 12.1 (5.4 to 25.1) | 23.3 (12.9 to 37.6) | 15.6 (7.8 to 28.7) | 32.3 (18.7 to 48.2) |
| At Week 4 | 18.2 (8.2 to 31.3) | 26.7 (14.0 to 41.6) | 28.1 (17.0 to 43.3) | 35.5 (21.3 to 51.8) |
| At Week 6 | 18.2 (8.2 to 31.3) | 30.0 (18.2 to 45.5) | 34.4 (20.7 to 50.0) | 45.2 (29.7 to 60.1) |
| At Follow-up visit | 9.1 (3.4 to 20.2) | 30.0 (18.2 to 45.5) | 21.9 (12.1 to 36.2) | 19.4 (8.8 to 32.7) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|----------------------------------|---------------------------|---------------------------------|----------------------------|----------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 28 | 30 | 30 | 27 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 90%) | | | | |
| At Week 1 | 10.7 (4.0 to 23.8) | 3.3 (0.4 to 14.0) | 3.3 (0.4 to 14.0) | 11.1 (4.2 to 24.8) |
| At Week 2 | 25.0 (13.9 to 40.0) | 10.0 (3.7 to 22.1) | 13.3 (5.9 to 27.9) | 33.3 (20.4 to 50.0) |
| At Week 3 | 32.1 (19.7 to 47.3) | 10.0 (3.7 to 22.1) | 20.0 (9.1 to 33.9) | 37.0 (22.1 to 54.7) |
| At Week 4 | 50.0 (33.3 to 66.7) | 10.0 (3.7 to 22.1) | 30.0 (18.2 to 45.5) | 37.0 (22.1 to 54.7) |
| At Week 6 | 50.0 (33.3 to 66.7) | 16.7 (8.3 to 30.8) | 33.3 (19.3 to 49.2) | 40.7 (24.8 to 58.3) |

| | | | | |
|--------------------|--------------------|--------------------|--------------------|-------------------|
| At Follow-up visit | 21.4 (9.8 to 36.6) | 20.0 (9.1 to 33.9) | 20.0 (9.1 to 33.9) | 7.4 (2.0 to 20.4) |
|--------------------|--------------------|--------------------|--------------------|-------------------|

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
| Statistical analysis description: | |
| At Week 1 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 63 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.245 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 3.3 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -5.4 |
| upper limit | 14.9 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: | |
| At Week 1 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 65 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.2575 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 3.1 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -5.3 |
| upper limit | 14 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: | |
| At Week 1 | |

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 64 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0087 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 16.1 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 5.7 |
| upper limit | 31 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
| Statistical analysis description: At Week 1 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 61 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0392 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 10.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 0.8 |
| upper limit | 25.4 |

| | |
|--|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
| Statistical analysis description: At Week 1 | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 1 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -11.2 |
| upper limit | 11.2 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

At Week 1

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1528 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 7.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -4.9 |
| upper limit | 22.5 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 2

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 63 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.4989 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 0.9 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -12.7 |
| upper limit | 15.2 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 2

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 65 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.5419 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 0.3 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -13.6 |
| upper limit | 14.2 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 1.0% Cream QD

Statistical analysis description:

At Week 2

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 64 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1362 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 10.3 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -5 |
| upper limit | 26.2 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 3.0% Cream QD

Statistical analysis description:

At Week 2

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 61 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0541 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 15.9 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -0.4 |
| upper limit | 33.9 |

| | |
|---|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
| Statistical analysis description: | |
| At Week 2 | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.3945 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 3.3 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -12 |
| upper limit | 19.5 |

| | |
|---|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
| Statistical analysis description: | |
| At Week 2 | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0201 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 23.3 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 3.9 |
| upper limit | 41.8 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 3

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 63 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1372 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 11.2 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -5.4 |
| upper limit | 28.2 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 0.3% Cream QD

Statistical analysis description:

At Week 3

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 65 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.3924 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 3.5 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -11.6 |
| upper limit | 19.1 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 1.0% Cream QD

Statistical analysis description:

At Week 3

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 64 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0311 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 20.1 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 2.4 |
| upper limit | 38.3 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
| Statistical analysis description: At Week 3 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 61 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0392 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 20 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 0.8 |
| upper limit | 38.1 |

| | |
|--|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
| Statistical analysis description: At Week 3 | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1541 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 10 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -6.2 |
| upper limit | 26.4 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

At Week 3

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0091 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 27 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 6.8 |
| upper limit | 45.4 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 0.1% Cream QD

Statistical analysis description:

At Week 4

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 63 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.2835 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 8.5 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -9.5 |
| upper limit | 27 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 0.3% Cream QD

Statistical analysis description:

At Week 4

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 65 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.27 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 9.9 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -8.7 |
| upper limit | 27.8 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: | |
| At Week 4 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 64 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0662 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 17.3 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -1.4 |
| upper limit | 36.2 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
| Statistical analysis description: | |
| At Week 4 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 61 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.005 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 31.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 9.2 |
| upper limit | 50.4 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

At Week 4

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0302 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 20 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 2.2 |
| upper limit | 38.3 |

Statistical analysis title

Vehicle Cream BID vs PF-06700841 1.0% Cream BID

Statistical analysis description:

At Week 4

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0091 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 27 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 6.8 |
| upper limit | 45.4 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 0.1% Cream QD

Statistical analysis description:

At Week 6

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 63 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1561 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 11.8 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -6.5 |
| upper limit | 30.2 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: | |
| At Week 6 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 65 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0753 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 16.2 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -2.7 |
| upper limit | 34.8 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: | |
| At Week 6 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 64 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0108 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 27 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 5.7 |
| upper limit | 46 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 6

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 61 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.005 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 31.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 9.2 |
| upper limit | 50.4 |

Statistical analysis title

Vehicle Cream BID vs PF-06700841 0.3% Cream BID

Statistical analysis description:

At Week 6

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0775 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 16.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -2.9 |
| upper limit | 35.7 |

Statistical analysis title

Vehicle Cream BID vs PF-06700841 1.0% Cream BID

Statistical analysis description:

At Week 6

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0243 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 24.1 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 3.4 |
| upper limit | 43.4 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
| Statistical analysis description: | |
| At follow-up visit | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 63 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0234 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 20.9 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 3.5 |
| upper limit | 38.8 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: | |
| At follow-up visit | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 65 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1134 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 12.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -2.8 |
| upper limit | 29.3 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
|-----------------------------------|---|

| | |
|---|---|
| Statistical analysis description: | |
| At follow-up visit | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 64 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1362 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 10.3 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -5 |
| upper limit | 26.2 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
| Statistical analysis description: | |
| At follow-up visit | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 61 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1029 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 12.3 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -3.4 |
| upper limit | 29.8 |

| | |
|---|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
| Statistical analysis description: | |
| At follow-up visit | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 1 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -17.9 |
| upper limit | 17.9 |

| | |
|---|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
| Statistical analysis description: | |
| At follow-up visit | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 57 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.8972 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -12.6 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -28.8 |
| upper limit | 3.5 |

Secondary: Percent Change From Baseline in Affected Body Surface Area (BSA) at Weeks 1, 2, 3, 4, 6 and Follow-up Visit

| | |
|--|---|
| End point title | Percent Change From Baseline in Affected Body Surface Area (BSA) at Weeks 1, 2, 3, 4, 6 and Follow-up Visit |
| End point description: | |
| <p>4 body regions: head and neck, upper limbs, trunk and lower limbs. Scalp, palms and soles were excluded. BSA calculated using handprint method. Number(No.)of handprints (size of subject's full palmer hand) fitting in affected area of body region was estimated. Maximum no. of handprints were 10 for head and neck, 20 for upper limbs, 30 for trunk and 40 for lower limbs. Surface area of body region equivalent to 1 handprint: 1 handprint = 10% for head and neck, 5% for upper limbs, 3.33% for trunk and 2.5% for lower limbs. Percent BSA for a body region was calculated as = total no. of handprints in a body region * % surface area equivalent to 1 handprint. Overall % BSA for an individual: arithmetic mean of % BSA of all 4 body regions, ranged from 0 to 100%, with higher values representing greater severity of AD. FAS population was analysed. N=number of subjects evaluable for this endpoint and "n"=subjects evaluable for each specified time point.</p> | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Weeks 1, 2, 3, 4, 6 and follow up visit (28 days after last dose of study drug = maximum up to Day 71) | |

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|--|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 36 | 33 | 35 |
| Units: Percent change | | | | |
| least squares mean (confidence interval 90%) | | | | |
| At Week 1(n=34,36,33,35,34,3436) | -2.4 (-12.2 to 7.4) | -2.9 (-12.5 to 6.8) | -16.2 (-26.2 to -6.2) | -19.9 (-29.6 to -10.2) |
| At Week 2(n=34,33,33,33,32, 32, 33, 32) | -15.3 (-28.0 to -2.6) | -7.2 (-20.2 to 5.8) | -38.1 (-51.0 to -25.2) | -43.6 (-56.5 to -30.8) |
| At Week 3(n=28,29,32,34,31,23,30,33) | -17.1 (-31.0 to -3.1) | -13.1 (-27.4 to 1.1) | -50.6 (-64.4 to -36.7) | -55.9 (-69.7 to -42.0) |
| At Week 4(n=30,28,33,32,32,25,32,32) | -25.9 (-39.8 to -12.0) | -20.1 (-34.4 to -5.7) | -55.8 (-69.5 to -42.1) | -57.9 (-71.7 to -44.0) |
| At Week 6(n=29,28,31,32,31,24,32,33) | -21.6 (-38.0 to -5.3) | -39.4 (-56.1 to -22.7) | -59.4 (-75.4 to -43.5) | -63.6 (-79.5 to -47.6) |
| At Follow-up visit(n=29,27,32,31,26,28,30,29) | -23.6 (-39.5 to -7.6) | -24.5 (-41.0 to -8.0) | -42.7 (-58.1 to -27.2) | -37.0 (-52.6 to -21.4) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|--|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 34 | 36 | 36 |
| Units: Percent change | | | | |
| least squares mean (confidence interval 90%) | | | | |
| At Week 1(n=34,36,33,35,34,3436) | -23.0 (-32.8 to -13.1) | 8.5 (-8.3 to 25.3) | -16.5 (-32.9 to -0.1) | -17.0 (-33.5 to -0.5) |
| At Week 2(n=34,33,33,33,32, 32, 33, 32) | -39.0 (-52.1 to -26.0) | -2.5 (-14.0 to 9.1) | -34.2 (-45.4 to -22.9) | -43.1 (-54.5 to -31.6) |
| At Week 3(n=28,29,32,34,31,23,30,33) | -49.2 (-63.2 to -35.1) | -25.2 (-39.2 to -11.1) | -39.8 (-53.0 to -26.6) | -44.0 (-57.1 to -30.9) |
| At Week 4(n=30,28,33,32,32,25,32,32) | -56.7 (-70.8 to -42.7) | -34.7 (-46.1 to -23.3) | -46.4 (-56.9 to -35.9) | -57.7 (-68.2 to -47.2) |
| At Week 6(n=29,28,31,32,31,24,32,33) | -60.3 (-76.4 to -44.1) | -31.2 (-42.5 to -20.0) | -48.9 (-59.3 to -38.6) | -65.0 (-75.3 to -54.7) |
| At Follow-up visit(n=29,27,32,31,26,28,30,29) | -55.2 (-71.8 to -38.6) | -26.3 (-47.5 to -5.2) | -31.6 (-52.0 to -11.3) | -24.6 (-45.2 to -4.1) |

Statistical analyses

| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
|--|---|
| Statistical analysis description: | |
| At Week 1: Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.4781 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -0.5 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -14.2 |
| upper limit | 13.3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 8.33 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: | |
| At Week 1: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 67 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0522 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -13.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -27.8 |
| upper limit | 0.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 8.47 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: | |
| At Week 1: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 69 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0187 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -17.5 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -31.4 |
| upper limit | -3.7 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 8.37 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
| Statistical analysis description: At Week 1: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 68 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.008 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -20.6 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -34.5 |
| upper limit | -6.6 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 8.45 |

| | |
|--|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
| Statistical analysis description: At Week 1: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0401 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -25 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -48.6 |
| upper limit | -1.5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 14.17 |

| | |
|---|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
| Statistical analysis description: | |
| At Week 1: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0379 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -25.5 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -49.2 |
| upper limit | -1.9 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 14.25 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
| Statistical analysis description: | |
| At Week 2: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.7678 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | 8.1 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -10.1 |
| upper limit | 26.3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 11.01 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: At Week 2: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 67 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0193 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -22.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -40.9 |
| upper limit | -4.7 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 10.94 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: At Week 2: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 69 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0052 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -28.3 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -46.5 |
| upper limit | -10.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 10.95 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
| Statistical analysis description: At Week 2: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 68 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0164 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -23.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -42 |
| upper limit | -5.5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 11.03 |

| | |
|--|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
| Statistical analysis description: At Week 2: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0008 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -31.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -47.8 |
| upper limit | -15.6 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 9.72 |

| | |
|--|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
| Statistical analysis description: At Week 2: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -40.6 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -57 |
| upper limit | -24.3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 9.86 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
| Statistical analysis description: At Week 3: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.6269 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | 3.9 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -16.1 |
| upper limit | 23.9 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 12.09 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: At Week 3: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 67 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0027 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -33.5 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -53.1 |
| upper limit | -13.8 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 11.87 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: At Week 3: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 69 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0007 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -38.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -58.5 |
| upper limit | -19.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 11.89 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
| Statistical analysis description: At Week 3: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 68 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0041 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -32.1 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -51.9 |
| upper limit | -12.3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 12 |

| | |
|--|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
| Statistical analysis description: At Week 3: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1054 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -14.6 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -33.9 |
| upper limit | 4.6 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 11.61 |

| | |
|---|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
| Statistical analysis description: | |
| At Week 3: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0542 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -18.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -38.1 |
| upper limit | 0.5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 11.62 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
| Statistical analysis description: | |
| At Week 4: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.6847 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | 5.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -14.2 |
| upper limit | 25.9 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 12.12 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: At Week 4: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 67 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0062 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -29.9 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -49.4 |
| upper limit | -10.3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 11.82 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: At Week 4: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 69 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.004 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -32 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -51.6 |
| upper limit | -12.3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 11.89 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
| Statistical analysis description: At Week 4: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 68 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0054 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -30.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -50.6 |
| upper limit | -11 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 11.97 |

| | |
|--|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
| Statistical analysis description: At Week 4: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1076 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -11.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -27.2 |
| upper limit | 3.9 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 9.35 |

| | |
|---|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
| Statistical analysis description: | |
| At Week 4: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0082 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -23 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -38.6 |
| upper limit | -7.3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 9.42 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
| Statistical analysis description: | |
| At Week 6: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1051 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -17.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -41.2 |
| upper limit | 5.6 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 14.14 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: At Week 6: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 67 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0034 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -37.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -60.6 |
| upper limit | -15 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 13.8 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: At Week 6: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 69 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0014 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -41.9 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -64.8 |
| upper limit | -19 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 13.83 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
| Statistical analysis description: At Week 6: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 68 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.003 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -38.6 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -61.6 |
| upper limit | -15.6 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 13.9 |

| | |
|--|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
| Statistical analysis description: At Week 6: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0289 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -17.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -33 |
| upper limit | -2.4 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 9.22 |

| | |
|---|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
| Statistical analysis description: At Week 6:MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0002 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -33.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -49.2 |
| upper limit | -18.4 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 9.27 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
| Statistical analysis description: At follow-up visit: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.4739 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -0.9 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -23.9 |
| upper limit | 22 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 13.88 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: | |
| At follow-up visit: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 67 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0789 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -19.1 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -41.3 |
| upper limit | 3.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 13.43 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: | |
| At follow-up visit: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 69 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1611 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -13.4 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -35.7 |
| upper limit | 8.9 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 13.5 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
| Statistical analysis description: | |
| At follow-up visit: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 68 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0124 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean Difference |
| Point estimate | -31.6 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -54.7 |
| upper limit | -8.5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 13.94 |

| | |
|--|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
| Statistical analysis description: | |
| At follow-up visit: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |

| | |
|---|------------------------------|
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.3828 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | -5.3 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -34.7 |
| upper limit | 24.1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 17.68 |

| | |
|--|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
| Statistical analysis description: | |
| At follow-up visit: MMRM contained fixed factors of treatment, visit, treatment-by-visit interaction and baseline value. | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 70 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.5383 |
| Method | Mixed Model Repeated Measure |
| Parameter estimate | LS Mean difference |
| Point estimate | 1.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -27.9 |
| upper limit | 31.3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 17.8 |

Secondary: Percentage of Subjects Achieving $\geq 75\%$ Improvement in Eczema Area and Severity Index Total Score (EASI-75) From Baseline at Weeks 1, 2, 3, 4 and 6: Non-responder Imputation

| | |
|-----------------|--|
| End point title | Percentage of Subjects Achieving $\geq 75\%$ Improvement in Eczema Area and Severity Index Total Score (EASI-75) From Baseline at Weeks 1, 2, 3, 4 and 6: Non-responder Imputation |
|-----------------|--|

End point description:

EASI:severity of subject's AD based on severity of AD clinical signs and % of BSA affected. Severity of clinical signs of AD scored separately for each of 4 body regions on 4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score was based upon % BSA with AD in each 4 body region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score = $0.1 \cdot A_h \cdot (E_h + I_h + Ex_h + L_h) + 0.2 \cdot A_u \cdot (E_u + I_u + Ex_u + L_u) + 0.3 \cdot A_t \cdot (E_t + I_t + Ex_t + L_t) + 0.4 \cdot A_l \cdot (E_l + I_l + Ex_l + L_l)$; A = EASI area score; E = erythema; I = induration/papulation; Ex = excoriation; L = lichenification; h = head and neck; u = upper limbs; t =

trunk; l = lower limbs. Total EASI score ranged from 0.0 to 72.0, higher scores = greater severity of AD.
 FAS: all subjects who were randomly assigned to study drug and applied at least 1 dose of study drug.
 NRI method: subjects with missing values were considered to be non-responders.

| | |
|----------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Weeks 1, 2, 3, 4 and 6 | |

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|----------------------------------|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 37 | 36 | 37 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 90%) | | | | |
| At Week 1 | 5.4 (1.4 to 15.5) | 0.0 (0.0 to 7.3) | 19.4 (10.7 to 32.8) | 5.4 (1.4 to 15.5) |
| At Week 2 | 8.1 (3.0 to 18.5) | 10.8 (4.8 to 22.2) | 27.8 (15.9 to 40.9) | 24.3 (14.5 to 37.0) |
| At Week 3 | 5.4 (1.4 to 15.5) | 16.2 (7.3 to 29.3) | 36.1 (22.9 to 50.0) | 43.2 (29.3 to 56.8) |
| At Week 4 | 24.3 (14.5 to 37.0) | 21.6 (11.2 to 34.3) | 38.9 (25.4 to 53.0) | 43.2 (29.3 to 56.8) |
| At Week 6 | 35.1 (22.2 to 49.3) | 32.4 (20.6 to 46.4) | 52.8 (38.0 to 67.2) | 54.1 (40.2 to 68.2) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|----------------------------------|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 36 | 36 | 36 | 37 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 90%) | | | | |
| At Week 1 | 16.7 (7.5 to 30.2) | 0.0 (0.0 to 7.5) | 13.9 (6.9 to 25.4) | 21.6 (11.2 to 34.3) |
| At Week 2 | 38.9 (25.4 to 53.0) | 13.9 (6.9 to 25.4) | 25.0 (14.9 to 38.0) | 32.4 (20.6 to 46.4) |
| At Week 3 | 41.7 (29.0 to 56.0) | 19.4 (10.7 to 32.8) | 19.4 (10.7 to 32.8) | 43.2 (29.3 to 56.8) |
| At Week 4 | 50.0 (35.3 to 64.7) | 22.2 (11.6 to 35.3) | 36.1 (22.9 to 50.0) | 48.6 (34.3 to 63.0) |
| At Week 6 | 50.0 (35.3 to 64.7) | 16.7 (7.5 to 30.2) | 36.1 (22.9 to 50.0) | 51.4 (37.0 to 65.7) |

Statistical analyses

| | |
|-----------------------------------|--|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
| Statistical analysis description: | |
| At Week 1 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream |

| | |
|---|-----------------------------|
| | QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.8964 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -5.4 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -16.1 |
| upper limit | 2 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: | |
| At Week 1 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0391 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 14 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 1 |
| upper limit | 28.2 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: | |
| At Week 1 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 1 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -10.8 |
| upper limit | 10.8 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
| Statistical analysis description: | |
| At Week 1 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0708 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 11.3 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -1.4 |
| upper limit | 25 |

| | |
|---|--|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
| Statistical analysis description: | |
| At Week 1 | |
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 72 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0122 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 13.9 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 4.7 |
| upper limit | 27 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

At Week 1

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0016 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 21.6 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 11 |
| upper limit | 35.6 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 0.1% Cream QD

Statistical analysis description:

At Week 2

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.395 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 2.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -9.8 |
| upper limit | 16.1 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 0.3% Cream QD

Statistical analysis description:

At Week 2

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0173 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 19.7 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 4.2 |
| upper limit | 35.6 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: | |
| At Week 2 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0327 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 16.2 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 1.4 |
| upper limit | 31 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
| Statistical analysis description: | |
| At Week 2 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0011 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 30.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 13.2 |
| upper limit | 46.6 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

At Week 2

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 72 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1348 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 11.1 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -5 |
| upper limit | 27.2 |

Statistical analysis title

Vehicle Cream BID vs PF-06700841 1.0% Cream BID

Statistical analysis description:

At Week 2

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0328 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 18.5 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 1.5 |
| upper limit | 34.8 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 0.1% Cream QD

Statistical analysis description:

At Week 3

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0769 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 10.8 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -1.8 |
| upper limit | 24.4 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: | |
| At Week 3 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0005 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 30.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 13.2 |
| upper limit | 46 |

| | |
|---|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
| Statistical analysis description: | |
| At Week 3 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 37.8 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 22.1 |
| upper limit | 53.1 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 3.0% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 3

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0001 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 36.3 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 19.7 |
| upper limit | 51.8 |

Statistical analysis title

Vehicle Cream BID vs PF-06700841 0.3% Cream BID

Statistical analysis description:

At Week 3

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 72 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 1 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 0 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -16.5 |
| upper limit | 16.5 |

Statistical analysis title

Vehicle Cream BID vs PF-06700841 1.0% Cream BID

Statistical analysis description:

At Week 3

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0173 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 23.8 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 4.5 |
| upper limit | 41.5 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
| Statistical analysis description: At Week 4 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.5663 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -2.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -19.9 |
| upper limit | 14.2 |

| | |
|--|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
| Statistical analysis description: At Week 4 | |
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1243 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 14.6 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -3.8 |
| upper limit | 32.6 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 1.0% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 4

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.046 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 18.9 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -0.5 |
| upper limit | 36.6 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 3.0% Cream QD

Statistical analysis description:

At Week 4

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.013 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 25.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 4.8 |
| upper limit | 43.3 |

Statistical analysis title

Vehicle Cream BID vs PF-06700841 0.3% Cream BID

Statistical analysis description:

At Week 4

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 72 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1194 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 13.9 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -4.2 |
| upper limit | 31.4 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

At Week 4

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0097 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 26.4 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 6.5 |
| upper limit | 44.4 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.1% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 6

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.1% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.5556 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | -2.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -21 |
| upper limit | 16.1 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream QD vs PF-06700841 0.3% Cream QD |
|-----------------------------------|---|

Statistical analysis description:

At Week 6

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 0.3% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0761 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 17.6 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -2.5 |
| upper limit | 36.5 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 1.0% Cream QD

Statistical analysis description:

At Week 6

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 1.0% Cream QD |
| Number of subjects included in analysis | 74 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0583 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 18.9 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -0.8 |
| upper limit | 37.6 |

Statistical analysis title

Vehicle Cream QD vs PF-06700841 3.0% Cream QD

Statistical analysis description:

At Week 6

| | |
|---|---|
| Comparison groups | Vehicle Cream Once Daily (QD) v PF-06700841 3.0% Cream QD |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1245 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 14.9 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -5 |
| upper limit | 33.7 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 0.3% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

At Week 6

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 0.3% Cream BID |
| Number of subjects included in analysis | 72 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0382 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 19.4 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 1.5 |
| upper limit | 36.5 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Vehicle Cream BID vs PF-06700841 1.0% Cream BID |
|-----------------------------------|---|

Statistical analysis description:

At Week 6

| | |
|---|--|
| Comparison groups | Vehicle Cream Twice Daily (BID) v PF-06700841 1.0% Cream BID |
| Number of subjects included in analysis | 73 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0011 |
| Method | Chan and Zhang Exact Method |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 34.7 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 13.2 |
| upper limit | 51.4 |

Secondary: Number of Subjects With Treatment-Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)

| | |
|-----------------|---|
| End point title | Number of Subjects With Treatment-Emergent Adverse Events |
|-----------------|---|

End point description:

An AE was any untoward medical occurrence in a subject who received investigational product without regard to possibility of causal relationship. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly; medically important events. Treatment-emergent AEs were events between first dose of investigational product and up to 28 days after the last dose of investigational product that were absent before treatment or that worsened relative to pretreatment state. AEs included both SAEs and non-SAEs. Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

| |
|---|
| Baseline (Day 1) up to at least 28 days after last dose of study drug (approximately up to Week 11) |
|---|

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|-----------------------------|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 37 | 36 | 37 |
| Units: Subjects | | | | |
| TEAEs | 18 | 17 | 11 | 12 |
| SAEs | 0 | 0 | 0 | 0 |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|-----------------------------|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 36 | 36 | 36 | 37 |
| Units: Subjects | | | | |
| TEAEs | 10 | 17 | 9 | 14 |
| SAEs | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Pre-defined Criteria For Vital Sign

| | |
|-----------------|---|
| End point title | Number of Subjects With Pre-defined Criteria For Vital Sign |
|-----------------|---|

End point description:

Pre-defined criteria included: 1) Diastolic blood pressure (DBP), a) sitting (S)DBP: change(C) of ≥ 20 millimeter of mercury (mmHg) increase (inc.), b) sitting DBP: change of ≥ 20 mmHg decrease(dec.), c) supine(Sup.) DBP: less than ($<$) 50 mmHg, d) supine DBP: change of ≥ 20 mmHg increase, e) supine DBP: change of ≥ 20 mmHg decrease; 2) Systolic blood pressure (SBP), a) sitting SBP: < 90 mmHg, b) sitting SBP: change of ≥ 30 mmHg increase, c) sitting SBP: change of ≥ 30 mmHg decrease, d) supine SBP: change of ≥ 30 mmHg increase, e) supine SBP: change of ≥ 30 mmHg decrease and f) Supine SBP: value(Val.) < 90 mmHg. Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "number of subjects analysed:" signifies number of subjects evaluable for this end point and "n" signifies subjects evaluable for the each

specified time point.

| | |
|-----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline up to Week 6 | |

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|---|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 21 | 20 | 25 | 18 |
| Units: Subjects | | | | |
| SDBP: Change \geq 20mmHg inc.(n=12,13,9,15,12,7,12,11) | 0 | 0 | 1 | 2 |
| SDBP: Change \geq 20mmHg dec.(n=12,13,9,15,12,7,12,11) | 1 | 0 | 0 | 1 |
| Supi.DBP: Val. <50 mmHg(n=21,20,25,18,21,19,22,22) | 0 | 0 | 0 | 0 |
| Sup.DBP: C \geq 20mmHg inc.(n=21,20,25,18,21,19,22,22) | 0 | 1 | 1 | 2 |
| Sup.DBP: C \geq 20mmHg dec.(n=21,20,25,18,21,19,22,22) | 0 | 0 | 0 | 0 |
| Sitting SBP: <90mmHg(n=12,13,9,15,12,7,12,11) | 0 | 0 | 0 | 1 |
| SittingSBP: C \geq 30mmHg inc.(n=12,13,9,15,12,7,12,11) | 0 | 0 | 0 | 1 |
| SittingSBP: C \geq 30mmHgdec.(n=12,13,9, 15,12,7,12,11) | 0 | 0 | 0 | 0 |
| SupineSBP: C \geq 30mmHginc.(n=21,20,2 5,18,21,19,22,22) | 1 | 0 | 1 | 0 |
| SupineSBP: C \geq 30mmHgdec.(n=21,20, 25,18,21,19,22,22) | 0 | 0 | 1 | 0 |
| Supine SBP: Val. <90mmHg(n=21,20,25,18,21,1 | 0 | 1 | 1 | 0 |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|---|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 21 | 19 | 22 | 22 |
| Units: Subjects | | | | |
| SDBP: Change \geq 20mmHg inc.(n=12,13,9,15,12,7,12,11) | 0 | 0 | 0 | 0 |
| SDBP: Change \geq 20mmHg dec.(n=12,13,9,15,12,7,12,11) | 0 | 1 | 0 | 0 |
| Supi.DBP: Val. <50 mmHg(n=21,20,25,18,21,19,22,22) | 0 | 1 | 0 | 0 |
| Sup.DBP: C \geq 20mmHg inc.(n=21,20,25,18,21,19,22,22) | 1 | 0 | 1 | 0 |
| Sup.DBP: C \geq 20mmHg dec.(n=21,20,25,18,21,19,22,22) | 0 | 0 | 1 | 0 |
| Sitting SBP: <90mmHg(n=12,13,9,15,12,7,12,11) | 0 | 0 | 0 | 0 |

| | | | | |
|--|---|---|---|---|
| SittingSBP:C>=30mmHg inc.(n=12,13,9,15,12,7,12,11) | 0 | 0 | 0 | 1 |
| SittingSBP:C>=30mmHgdec.(n=12,13,9, 15,12,7,12,11) | 1 | 0 | 0 | 0 |
| SupineSBP:C>=30mmHginc.(n=21,20,2 5,18,21,19,22,22) | 0 | 1 | 1 | 0 |
| SupineSBP:C>=30mmHgdec.(n=21,20, 25,18,21,19,22,22) | 0 | 0 | 2 | 0 |
| Supine SBP:Val.<90mmHg(n=21,20,25,18,21,1 | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Laboratory Abnormalities

| End point title | Number of Subjects With Laboratory Abnormalities |
|---|--|
| End point description: Hemoglobin(HGB),hematocrit,erythrocytes(ery.),HDL cholesterol(chl.)<0.8*lower limit of normal(LLN);reticulocytes (ret.), ret./ery.(%)<0.5*LLN,>1.5*upper limit of normal(ULN);ery.mean corpuscular(EMC) volume,EMC HGB,EMC HGBconcentration,potassium,chloride,calcium,bicarbonate<0.9*LLN,>1.1*ULN;platelets<0.5*LLN,>1.75*ULN;leukocytes (leu.),glucose<0.6*LLN,>1.5*ULN;lymphocytes (lym.),lym./leu.(%),neutrophils(neu.),neu./leu.(%),protein,albumin <0.8*LLN,>1.2*ULN;basophils(bas.),bas./leu.(%),eosinophils(eos.),eos./leu.,monocytes(mon.),mon./leu.(%),urate >1.2*ULN;bilirubin (total,direct,indirect)>1.5*ULN;aspartate/alanine aminotransferase,gamma glutamyl transferase, lactate dehydrogenase,alkaline phosphatase>3.0*ULN;urea nitrogen, creatinine,triglycerides,chl.>1.3*ULN; sodium <0.95*LLN,>1.05*ULN; creatine kinase >2.0*ULN;Urine: pH<4.5,>8;glucose,ketones, | |
| End point type | Secondary |
| End point timeframe: Baseline (Day 1) up to at least 28 days after last dose of study drug (approximately up to Week 11) | |

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|-----------------------------|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 35 | 35 | 37 |
| Units: Subjects | 26 | 22 | 23 | 22 |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|-----------------------------|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 35 | 36 | 36 | 36 |
| Units: Subjects | 16 | 21 | 24 | 24 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Significant Change in Electrocardiogram (ECG) Findings

| | |
|-----------------|---|
| End point title | Number of Subjects With Clinically Significant Change in Electrocardiogram (ECG) Findings |
|-----------------|---|

End point description:

Clinically significant ECG criteria included PR interval: value greater than (>) 280 millisecond (msec), percentage change greater than equal to (\geq) 25/50 percentage, QRS interval: value >120 msec, percentage change \geq 50% and QT interval corrected using the Fridericia's formula (QTCF) value 450 msec and $30 \leq \text{change} < 60$. Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "number of subjects analysed" signifies number of subjects evaluable for this endpoint.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline up to Week 6

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|-------------------------------------|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 6 | 7 | 9 |
| Units: Subjects | | | | |
| PR interval : value >280 | 0 | 0 | 0 | 0 |
| PR interval : %change \geq 25/50% | 0 | 1 | 1 | 0 |
| QRS interval: value >120 | 0 | 0 | 0 | 0 |
| QRS interval: %Change \geq 50% | 0 | 0 | 0 | 0 |
| QTCF: 450 | 0 | 0 | 1 | 1 |
| QTCF: $30 \leq \text{Change} < 60$ | 0 | 1 | 1 | 1 |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|-------------------------------------|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 6 | 7 | 7 |
| Units: Subjects | | | | |
| PR interval : value >280 | 1 | 0 | 0 | 0 |
| PR interval : %change \geq 25/50% | 1 | 0 | 2 | 0 |
| QRS interval: value >120 | 0 | 0 | 1 | 1 |
| QRS interval: %Change \geq 50% | 0 | 1 | 0 | 0 |
| QTCF: 450 | 0 | 1 | 0 | 0 |
| QTCF: $30 \leq \text{Change} < 60$ | 1 | 2 | 1 | 0 |

Statistical analyses

Secondary: Change From Baseline in Clinical Chemistry-Lactate Dehydrogenase Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit

| | |
|-----------------|--|
| End point title | Change From Baseline in Clinical Chemistry-Lactate Dehydrogenase Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit |
|-----------------|--|

End point description:

Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "Number of Subjects Analysed" signifies subjects evaluable for this end point and "n" signifies subjects evaluable for the each specified time point. Change at follow-up= CAF.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Weeks 1, 2, 4, 6 and follow up visit (28 days after last dose of study drug = maximum up to Day 71)

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|---|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 32 | 32 | 32 | 33 |
| Units: Units per litre | | | | |
| arithmetic mean (standard deviation) | | | | |
| Change at week 1(n=32,32,32,30,32,32,34,33) | 0.4 (± 25.99) | -7.4 (± 30.20) | -5.3 (± 16.99) | -9.3 (± 22.65) |
| Change at week 2(n=32,27,30,33,27,28,31,30) | -8.8 (± 21.56) | -7.8 (± 27.99) | -1.9 (± 18.18) | -8.8 (± 23.70) |
| Change at week 4(n=26,27,30,31,30,24,27,29) | -8.6 (± 23.93) | -5.4 (± 22.87) | -9.3 (± 19.61) | -12.1 (± 28.54) |
| Change at week 6(n=30,26,31,31,28,23,31,32) | -8.8 (± 18.25) | -8.1 (± 32.02) | -1.5 (± 32.42) | -6.4 (± 28.53) |
| CAF visit(n=26,28,31,30,27,30,30,26) | -12.3 (± 24.82) | -12.0 (± 28.83) | 4.0 (± 43.45) | -2.7 (± 26.27) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|---|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 32 | 32 | 34 | 33 |
| Units: Units per litre | | | | |
| arithmetic mean (standard deviation) | | | | |
| Change at week 1(n=32,32,32,30,32,32,34,33) | -18.4 (± 33.42) | -8.0 (± 34.51) | -8.0 (± 19.37) | -4.3 (± 29.08) |
| Change at week 2(n=32,27,30,33,27,28,31,30) | -15.8 (± 42.19) | -0.3 (± 22.81) | -8.0 (± 22.31) | -4.9 (± 24.49) |
| Change at week 4(n=26,27,30,31,30,24,27,29) | -16.3 (± 33.97) | -1.0 (± 29.29) | -19.5 (± 19.94) | -3.7 (± 24.96) |
| Change at week 6(n=30,26,31,31,28,23,31,32) | -18.2 (± 33.86) | -9.7 (± 20.68) | -11.2 (± 22.34) | -7.0 (± 24.65) |
| CAF visit(n=26,28,31,30,27,30,30,26) | -15.1 (± 38.23) | -11.3 (± 29.39) | -13.3 (± 25.37) | 0.2 (± 16.48) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Clinical Chemistry- Protein and Albumin Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit

| | |
|-----------------|---|
| End point title | Change From Baseline in Clinical Chemistry- Protein and Albumin Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit |
|-----------------|---|

End point description:

Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "Number of Subjects Analyzed" signifies subjects evaluable for this end point and "n" signifies subjects evaluable for the each specified time point. CAW: change at week. CAF: change at follow-up.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Weeks 1, 2, 4, 6 and follow up visit (28 days after last dose of study drug = maximum up to Day 71)

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|---|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 35 | 33 | 35 |
| Units: Gram per decilitre | | | | |
| arithmetic mean (standard deviation) | | | | |
| Protein: CAW 1(n=34,35,33,35,34,34,36,35) | -0.01 (± 0.439) | -0.04 (± 0.294) | -0.14 (± 0.433) | -0.04 (± 0.264) |
| Protein:CAW2(n=34,33,32,34,32,30,33, 32) | -0.09 (± 0.383) | 0.03 (± 0.303) | -0.18 (± 0.402) | -0.01 (± 0.275) |
| Protein: CAW4(n- 29,28,33,31,32,24,31,30) | -0.10 (± 0.380) | 0.07 (± 0.315) | -0.08 (± 0.429) | -0.03 (± 0.341) |
| Protein: CAW6(n=30,27,31,32,31,24,32,33) | -0.13 (± 0.403) | 0.13 (± 0.379) | -0.19 (± 0.452) | 0.01 (± 0.368) |
| Protein: CAFvisit(n=30,29,32,32,29,31,32,30) | -0.07 (± 0.341) | 0.05 (± 0.457) | -0.15 (± 0.481) | -0.04 (± 0.404) |
| Albumin:CAW 1(n=34,35,33,35,34,34,36,35) | -0.04 (± 0.269) | -0.05 (± 0.205) | -0.10 (± 0.283) | -0.02 (± 0.177) |
| Albumin:CAW 2(n=34,33,32,34,32,30,33,32) | -0.06 (± 0.235) | 0.02 (± 0.201) | -0.10 (± 0.256) | -0.02 (± 0.204) |
| Albumin: CAW4(n- 29,28,33,31,32,24,31,30) | -0.08 (± 0.245) | 0.07 (± 0.172) | -0.08 (± 0.285) | 0.01 (± 0.239) |
| Albumin:CAW 6(n=30,27,31,32,31,24,32,33) | -0.08 (± 0.259) | 0.08 (± 0.245) | -0.14 (± 0.333) | -0.02 (± 0.269) |
| Albumin:CAF visit(n=30,29,32,32,29,31,32,30) | -0.06 (± 0.247) | 0.10 (± 0.260) | -0.09 (± 0.277) | -0.04 (± 0.295) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|---|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 36 | 36 | 35 |
| Units: Gram per decilitre | | | | |
| arithmetic mean (standard deviation) | | | | |
| Protein: CAW 1(n=34,35,33,35,34,34,36,35) | -0.03 (± 0.421) | -0.10 (± 0.360) | -0.01 (± 0.344) | -0.02 (± 0.301) |
| Protein:CAW2(n=34,33,32,34,32,30,33, 32) | 0.01 (± 0.561) | 0.02 (± 0.503) | -0.04 (± 0.286) | -0.10 (± 0.299) |
| Protein: CAW4(n- 29,28,33,31,32,24,31,30) | -0.04 (± 0.465) | -0.18 (± 0.292) | -0.15 (± 0.242) | 0.03 (± 0.280) |
| Protein: CAW6(n=30,27,31,32,31,24,32,33) | -0.03 (± 0.405) | -0.10 (± 0.424) | -0.09 (± 0.368) | -0.09 (± 0.310) |
| Protein: CAFvisit(n=30,29,32,32,29,31,32,30) | 0.03 (± 0.481) | -0.18 (± 0.471) | -0.09 (± 0.398) | 0.02 (± 0.299) |
| Albumin:CAW 1(n=34,35,33,35,34,34,36,35) | 0.00 (± 0.256) | -0.05 (± 0.218) | -0.03 (± 0.246) | 0.00 (± 0.169) |
| Albumin:CAW 2(n=34,33,32,34,32,30,33,32) | -0.01 (± 0.283) | 0.02 (± 0.266) | -0.03 (± 0.174) | -0.06 (± 0.202) |
| Albumin: CAW4(n- 29,28,33,31,32,24,31,30) | 0.04 (± 0.292) | -0.10 (± 0.232) | -0.08 (± 0.180) | 0.03 (± 0.224) |
| Albumin:CAW 6(n=30,27,31,32,31,24,32,33) | -0.00 (± 0.218) | -0.03 (± 0.252) | -0.07 (± 0.244) | -0.05 (± 0.227) |
| Albumin:CAF visit(n=30,29,32,32,29,31,32,30) | -0.01 (± 0.346) | -0.09 (± 0.262) | -0.02 (± 0.211) | 0.06 (± 0.181) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Clinical Chemistry- Urea Nitrogen, Urate, Calcium and Glucose Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit

| | |
|-----------------|---|
| End point title | Change From Baseline in Clinical Chemistry- Urea Nitrogen, Urate, Calcium and Glucose Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit |
|-----------------|---|

End point description:

Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "Number of Subjects Analysed" signifies subjects evaluable for this end point and "n" signifies subjects evaluable for the each specified time point.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Weeks 1, 2, 4, 6 and follow up visit (28 days after last dose of study drug = maximum up to Day 71)

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|---|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 35 | 33 | 35 |
| Units: Microgram per decilitre | | | | |
| arithmetic mean (standard deviation) | | | | |
| Urea nitrogen:CAW 1(n=34,35,33,35,34,34,36,35) | 0.9 (± 4.57) | 0.6 (± 3.04) | 0.1 (± 3.12) | 1.0 (± 3.19) |
| Urea nitrogen:CAW2(n=34,33,32,34,32,30,3 | 0.8 (± 3.89) | 0.0 (± 2.71) | 0.6 (± 3.54) | 0.9 (± 3.18) |
| Urea nitrogen:CAW4(n- 29,28,33,31,32,24,31,30) | 0.6 (± 3.39) | 0.0 (± 3.04) | -0.0 (± 2.67) | 1.4 (± 3.06) |
| Urea nitrogen:CAW 6(n=30,27,31,32,31,24,32,33) | 0.7 (± 2.84) | -0.2 (± 3.11) | -0.6 (± 3.61) | 0.9 (± 3.27) |
| Urea nitrogen:CAFvisit(n=30,29,32,32,29,31, | 0.0 (± 3.17) | -0.3 (± 3.13) | 0.4 (± 2.60) | 1.2 (± 4.22) |
| Urate:CAW1(n=34,35,33,35,34,34,36,3 5) | 0.16 (± 0.807) | 0.01 (± 0.606) | 0.16 (± 0.678) | -0.01 (± 0.561) |
| Urate: CAW2(n=34,33,32,34,32,30,33,32) | 0.30 (± 0.990) | -0.11 (± 0.655) | 0.12 (± 0.617) | -0.03 (± 0.649) |
| Urate: CAW 4(n- 29,28,33,31,32,24,31,30) | 0.21 (± 0.497) | 0.14 (± 0.731) | 0.06 (± 0.756) | -0.06 (± 0.621) |
| Urate: CAW 6(n=30,27,31,32,31,24,32,33) | 0.13 (± 0.728) | 0.07 (± 0.984) | -0.02 (± 0.831) | 0.06 (± 0.630) |
| Urate: CAW visit(n=30,29,32,32,29,31,32,30) | -0.11 (± 0.721) | -0.33 (± 0.753) | 0.05 (± 0.763) | -0.21 (± 0.554) |
| Calcium:CAW 1(n=34,35,33,35,34,34,36,35) | 0.01 (± 0.419) | 0.01 (± 0.259) | -0.06 (± 0.377) | -0.02 (± 0.248) |
| Calcium:CAW2(n=34,33,32,34,32,30,33 ,32) | -0.08 (± 0.417) | 0.00 (± 0.268) | -0.10 (± 0.362) | 0.05 (± 0.296) |
| Calcium:CAW4(n- 29,28,33,31,32,24,31,30) | -0.04 (± 0.354) | 0.11 (± 0.329) | -0.07 (± 0.345) | 0.05 (± 0.272) |
| Calcium:CAW6(n=30,27,31,32,31,24,32 ,33) | -0.04 (± 0.355) | 0.10 (± 0.303) | -0.21 (± 0.393) | 0.03 (± 0.315) |
| Calcium:CAFvisit(n=30,29,32,32,29,31, 32,30) | 0.00 (± 0.317) | -0.01 (± 0.345) | -0.08 (± 0.409) | 0.00 (± 0.323) |
| Glucose:CAW 1(n=34,35,33,34,34,33,36,35) | 4.9 (± 8.73) | 5.7 (± 13.97) | 3.4 (± 14.62) | 4.5 (± 8.60) |
| Glucose:CAW2(n=33,33,32,34,32,30,33 ,32) | 9.7 (± 23.71) | 1.2 (± 17.34) | 0.6 (± 10.97) | 3.2 (± 12.63) |
| Glucose:CAW 4(n- 29,28,33,31,32,24,31,30) | 7.3 (± 15.60) | 0.5 (± 12.50) | -1.2 (± 15.86) | 4.5 (± 13.99) |
| Glucose:CAW6(n=30,27,31,32,31,24,32 ,33) | 3.5 (± 9.19) | 2.4 (± 17.55) | -1.7 (± 10.62) | 2.1 (± 13.80) |
| Glucose:CAFvisit(n=30,29,32,32,29,31, 32,30) | 4.5 (± 11.58) | 2.2 (± 11.45) | 4.8 (± 13.28) | 4.6 (± 14.77) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|---|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 34 | 36 | 35 |
| Units: Microgram per decilitre | | | | |
| arithmetic mean (standard deviation) | | | | |
| Urea nitrogen:CAW 1(n=34,35,33,35,34,34,36,35) | 1.0 (± 3.05) | 0.2 (± 2.19) | 0.4 (± 3.38) | -0.1 (± 2.65) |

| | | | | |
|---|--------------------|--------------------|--------------------|--------------------|
| Urea nitrogen:CAW2(n=34,33,32,34,32,30,3 | 0.5 (± 3.63) | 0.6 (± 4.19) | 0.8 (± 2.99) | 0.4 (± 3.28) |
| Urea nitrogen:CAW4(n- 29,28,33,31,32,24,31,30) | 0.5 (± 3.84) | -0.7 (± 2.96) | 1.3 (± 2.81) | -0.2 (± 3.61) |
| Urea nitrogen:CAW 6(n=30,27,31,32,31,24,32,33) | 0.3 (± 3.82) | -0.8 (± 3.24) | 0.2 (± 3.52) | -0.4 (± 3.69) |
| Urea nitrogen:CAFvisit(n=30,29,32,32,29,31, | 0.2 (± 2.87) | 0.8 (± 3.78) | 0.5 (± 3.42) | 0.1 (± 3.78) |
| Urate:CAW1(n=34,35,33,35,34,34,36,3 5) | 0.00 (± 0.739) | 0.05 (± 0.661) | -0.02 (± 0.704) | -0.14 (± 0.890) |
| Urate: CAW2(n=34,33,32,34,32,30,33,32) | -0.15 (± 0.842) | 0.27 (± 1.025) | -0.03 (± 0.718) | -0.37 (± 1.059) |
| Urate: CAW 4(n- 29,28,33,31,32,24,31,30) | -0.14 (± 0.856) | 0.22 (± 0.806) | -0.21 (± 0.663) | -0.16 (± 0.713) |
| Urate: CAW 6(n=30,27,31,32,31,24,32,33) | -0.02 (± 0.649) | 0.06 (± 0.534) | -0.11 (± 0.827) | -0.21 (± 1.084) |
| Urate: CAW visit(n=30,29,32,32,29,31,32,30) | -0.02 (± 0.810) | 0.02 (± 0.590) | -0.08 (± 0.677) | -0.20 (± 0.989) |
| Calcium:CAW 1(n=34,35,33,35,34,34,36,35) | 0.07 (± 0.386) | -0.02 (± 0.303) | -0.01 (± 0.295) | 0.09 (± 0.318) |
| Calcium:CAW2(n=34,33,32,34,32,30,33 ,32) | 0.07 (± 0.423) | 0.03 (± 0.389) | -0.10 (± 0.293) | -0.01 (± 0.244) |
| Calcium:CAW4(n- 29,28,33,31,32,24,31,30) | 0.00 (± 0.376) | -0.08 (± 0.309) | -0.03 (± 0.257) | 0.10 (± 0.341) |
| Calcium:CAW6(n=30,27,31,32,31,24,32 ,33) | 0.00 (± 0.397) | -0.05 (± 0.335) | -0.05 (± 0.464) | -0.04 (± 0.337) |
| Calcium:CAFvisit(n=30,29,32,32,29,31, 32,30) | 0.10 (± 0.441) | -0.05 (± 0.419) | 0.01 (± 0.378) | 0.05 (± 0.356) |
| Glucose:CAW 1(n=34,35,33,34,34,33,36,35) | 4.4 (± 16.14) | 4.5 (± 29.90) | 5.6 (± 13.14) | 3.3 (± 13.58) |
| Glucose:CAW2(n=33,33,32,34,32,30,33 ,32) | 3.1 (± 10.00) | -1.9 (± 13.51) | 7.9 (± 16.67) | 2.7 (± 18.07) |
| Glucose:CAW 4(n- 29,28,33,31,32,24,31,30) | 2.8 (± 20.20) | 1.3 (± 24.01) | 10.7 (± 26.13) | 3.4 (± 18.33) |
| Glucose:CAW6(n=30,27,31,32,31,24,32 ,33) | -0.5 (± 9.77) | -3.4 (± 16.37) | 4.3 (± 12.23) | 1.5 (± 12.62) |
| Glucose:CAFvisit(n=30,29,32,32,29,31, 32,30) | 6.0 (± 13.79) | 6.2 (± 16.75) | 9.1 (± 17.21) | 2.0 (± 22.43) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Clinical Chemistry- Sodium, Potassium, Chloride and Bicarbonate Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit

| | |
|-----------------|---|
| End point title | Change From Baseline in Clinical Chemistry- Sodium, Potassium, Chloride and Bicarbonate Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit |
|-----------------|---|

End point description:

Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "Number of Subjects Analysed" signifies subjects evaluable for this end point and "n" signifies subjects evaluable for the each specified time point.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Weeks 1, 2, 4, 6 and follow up visit (28 days after last dose of study drug = maximum up to Day 71)

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|---|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 35 | 33 | 35 |
| Units: Milliequivalents per litre | | | | |
| arithmetic mean (standard deviation) | | | | |
| Sodium:CAW 1(n=34,35,33,35,34,34,36,35) | 0.1 (± 2.34) | -0.0 (± 1.77) | -0.7 (± 2.04) | -0.6 (± 2.17) |
| Sodium:CAW2(n=34,33,32,34,32,30,33,32) | -0.5 (± 2.23) | -0.3 (± 1.89) | -0.1 (± 2.39) | -0.2 (± 2.18) |
| Sodium:CAW4(n=29,28,33,31,32,24,31,30) | -0.3 (± 2.70) | 0.6 (± 1.83) | -0.2 (± 2.44) | -0.7 (± 2.71) |
| Sodium:CAW6(n=30,27,31,32,31,24,32,33) | -0.8 (± 2.31) | 0.0 (± 2.39) | -0.2 (± 2.23) | -0.9 (± 2.40) |
| Sodium:CAF visit(n=30,29,32,32,29,31,32,30) | -0.4 (± 3.26) | 0.5 (± 2.50) | -0.1 (± 2.45) | -0.3 (± 2.41) |
| Potassium:CAW1(n=34,35,33,35,34,34,36,34) | -0.00 (± 0.363) | 0.08 (± 0.282) | 0.03 (± 0.372) | 0.02 (± 0.347) |
| Potassium:CAW2(n=33,33,32,34,32,30,33,32) | -0.14 (± 0.367) | 0.04 (± 0.298) | -0.07 (± 0.338) | 0.04 (± 0.359) |
| Potassium:CAW4(n=29,28,33,31,32,24,31,30) | 0.01 (± 0.389) | -0.06 (± 0.285) | -0.02 (± 0.350) | -0.01 (± 0.327) |
| Potassium:CAW6(n=30,27,31,32,31,24,32,33) | -0.09 (± 0.373) | 0.03 (± 0.295) | -0.06 (± 0.332) | 0.03 (± 0.407) |
| Potassium:CAF visit(n=30,29,32,32,29,31,32,30) | -0.11 (± 0.379) | 0.10 (± 0.375) | 0.03 (± 0.394) | 0.04 (± 0.351) |
| Chloride:CAW1(n=34,35,33,35,34,34,36,35) | 0.1 (± 2.11) | 0.3 (± 1.86) | 0.3 (± 1.57) | 0.0 (± 2.54) |
| Chloride:CAW2(n=34,33,32,34,32,30,33,32) | -0.2 (± 2.52) | -0.2 (± 2.08) | 0.7 (± 2.03) | 0.2 (± 2.50) |
| Chloride:CAW4(n=29,28,33,31,32,24,31,30) | 0.3 (± 2.05) | 0.6 (± 1.89) | 0.2 (± 2.68) | -0.4 (± 2.23) |
| Chloride:CAW6(n=30,27,31,32,31,24,32,33) | -0.6 (± 1.98) | 0.1 (± 2.27) | 0.0 (± 2.34) | -0.5 (± 2.44) |
| Chloride:CAFvisit(n=30,29,32,32,29,31,32,30) | 0.6 (± 2.97) | -0.3 (± 2.16) | 0.8 (± 2.64) | 0.1 (± 2.41) |
| Bicarbonate:CAW1(n=34,35,33,33,34,33,36,35) | 0.13 (± 2.548) | -0.38 (± 1.759) | -0.20 (± 1.965) | -0.18 (± 1.768) |
| Bicarbonate: CAW2(n=34,33,32,34,31,30,33,32) | 0.08 (± 2.229) | -0.40 (± 2.151) | -0.51 (± 1.956) | 0.10 (± 2.129) |
| Bicarbonate:CAW4(n=29,28,33,31,32,24,30,30) | 0.21 (± 2.739) | 0.05 (± 2.128) | -0.24 (± 2.484) | 0.34 (± 1.868) |
| Bicarbonate:CAW6(n=30,27,31,32,31,24,32,33) | 0.52 (± 2.560) | -0.44 (± 2.598) | 0.66 (± 2.132) | 0.27 (± 2.204) |
| Bicarbonate:CAFvisit(n=30,29,32,32,29,31,32,30) | -0.02 (± 2.916) | 0.66 (± 2.209) | 0.41 (± 2.056) | 0.75 (± 2.386) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|-----------------------------|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 34 | 36 | 35 |

| | | | | |
|---|-----------------|-----------------|-----------------|-----------------|
| Units: Milliequivalents per litre | | | | |
| arithmetic mean (standard deviation) | | | | |
| Sodium:CAW1(n=34,35,33,35,34,34,36,35) | -0.4 (± 3.50) | 0.4 (± 1.97) | 0.0 (± 2.08) | -0.1 (± 3.39) |
| Sodium:CAW2(n=34,33,32,34,32,30,33,32) | -0.4 (± 3.61) | -0.2 (± 2.61) | -0.5 (± 2.20) | -0.3 (± 3.45) |
| Sodium:CAW4(n=29,28,33,31,32,24,31,30) | -0.4 (± 3.08) | -0.4 (± 2.72) | -0.1 (± 1.77) | -0.3 (± 3.28) |
| Sodium:CAW6(n=30,27,31,32,31,24,32,33) | -0.9 (± 3.55) | 0.9 (± 2.50) | -0.1 (± 2.23) | -0.5 (± 2.49) |
| Sodium:CAF visit(n=30,29,32,32,29,31,32,30) | -0.8 (± 3.59) | 0.7 (± 1.94) | -0.1 (± 2.46) | 0.1 (± 3.32) |
| Potassium:CAW1(n=34,35,33,35,34,34,36,34) | 0.07 (± 0.343) | 0.01 (± 0.337) | 0.00 (± 0.429) | 0.20 (± 0.464) |
| Potassium:CAW2(n=33,33,32,34,32,30,33,32) | 0.07 (± 0.346) | 0.00 (± 0.245) | -0.16 (± 0.438) | -0.02 (± 0.322) |
| Potassium:CAW4(n=29,28,33,31,32,24,31,30) | 0.05 (± 0.375) | -0.09 (± 0.300) | -0.03 (± 0.415) | 0.26 (± 0.350) |
| Potassium:CAW6(n=30,27,31,32,31,24,32,33) | -0.06 (± 0.262) | -0.06 (± 0.309) | -0.10 (± 0.355) | 0.09 (± 0.388) |
| Potassium:CAF visit(n=30,29,32,32,29,31,32,30) | 0.12 (± 0.358) | 0.05 (± 0.293) | -0.09 (± 0.475) | 0.26 (± 0.460) |
| Chloride:CAW1(n=34,35,33,35,34,34,36,35) | 0.0 (± 2.66) | 0.6 (± 2.11) | 0.5 (± 2.02) | 0.5 (± 2.83) |
| Chloride:CAW2(n=34,33,32,34,32,30,33,32) | -0.2 (± 2.87) | 0.4 (± 2.70) | 0.4 (± 2.15) | 0.2 (± 2.99) |
| Chloride:CAW4(n=29,28,33,31,32,24,31,30) | -0.3 (± 2.16) | 0.3 (± 3.28) | 1.0 (± 2.21) | -0.2 (± 2.57) |
| Chloride:CAW6(n=30,27,31,32,31,24,32,33) | -0.4 (± 3.05) | 0.5 (± 2.93) | 0.9 (± 2.73) | 0.0 (± 2.32) |
| Chloride:CAFvisit(n=30,29,32,32,29,31,32,30) | -0.4 (± 2.90) | 1.3 (± 2.11) | 0.3 (± 2.35) | 0.4 (± 3.16) |
| Bicarbonate:CAW1(n=34,35,33,33,34,33,36,35) | 0.28 (± 1.638) | 0.09 (± 2.209) | -0.21 (± 2.388) | -0.02 (± 1.651) |
| Bicarbonate:CAW2(n=34,33,32,34,31,30,33,32) | -0.13 (± 1.931) | -0.15 (± 2.341) | -0.60 (± 2.354) | -0.07 (± 1.828) |
| Bicarbonate:CAW4(n=29,28,33,31,32,24,30,30) | 0.02 (± 2.011) | 0.14 (± 1.286) | -0.00 (± 2.695) | 0.02 (± 1.704) |
| Bicarbonate:CAW6(n=30,27,31,32,31,24,32,33) | 0.12 (± 2.407) | 0.63 (± 2.096) | -0.19 (± 2.038) | -0.20 (± 2.217) |
| Bicarbonate:CAFvisit(n=30,29,32,32,29,31,32,30) | 0.43 (± 2.162) | 0.08 (± 1.643) | 0.18 (± 2.300) | 1.09 (± 2.049) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hematology- Hemoglobin Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit

| | |
|-----------------|--|
| End point title | Change From Baseline in Hematology- Hemoglobin Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit |
|-----------------|--|

End point description:

Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "Number of Subjects Analysed" signifies subjects evaluable for this end point and "n" signifies subjects evaluable for the each specified time point.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Weeks 1, 2, 4, 6 and follow up visit (28 days after last dose of study drug = maximum up to Day 71)

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|--------------------------------------|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 37 | 33 | 34 |
| Units: Gram per decilitre | | | | |
| arithmetic mean (standard deviation) | | | | |
| CAW 1(n=34,35,32,34,34,33,35,34) | -0.01 (± 0.790) | -0.22 (± 0.620) | -0.36 (± 0.775) | -0.12 (± 0.678) |
| CAW 2(n=34,33,32,34,32,30,33,31) | -0.16 (± 0.636) | -0.09 (± 0.566) | -0.64 (± 0.715) | -0.24 (± 0.657) |
| CAW 4(n=28,27,33,31,32,25,30,30) | 0.03 (± 0.725) | -0.17 (± 0.630) | -0.48 (± 0.659) | -0.25 (± 0.628) |
| CAW 6(n=29,27,31,32,31,24,32,33) | -0.13 (± 0.832) | -0.06 (± 0.614) | -0.48 (± 0.767) | -0.03 (± 0.617) |
| CAF visit(n=30,29,30,32,30,31,32,30) | 0.05 (± 0.613) | -0.04 (± 0.717) | -0.49 (± 0.777) | -0.09 (± 0.784) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|--------------------------------------|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 33 | 35 | 34 |
| Units: Gram per decilitre | | | | |
| arithmetic mean (standard deviation) | | | | |
| CAW 1(n=34,35,32,34,34,33,35,34) | -0.26 (± 0.726) | -0.19 (± 0.698) | -0.21 (± 0.584) | -0.27 (± 0.679) |
| CAW 2(n=34,33,32,34,32,30,33,31) | -0.22 (± 0.798) | -0.16 (± 0.830) | -0.25 (± 0.625) | -0.32 (± 0.793) |
| CAW 4(n=28,27,33,31,32,25,30,30) | -0.06 (± 0.821) | -0.27 (± 0.789) | -0.32 (± 0.701) | -0.20 (± 0.658) |
| CAW 6(n=29,27,31,32,31,24,32,33) | -0.11 (± 0.775) | -0.22 (± 0.724) | -0.21 (± 0.833) | -0.28 (± 0.683) |
| CAF visit(n=30,29,30,32,30,31,32,30) | 0.00 (± 0.773) | -0.27 (± 0.756) | -0.12 (± 0.826) | -0.18 (± 0.740) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hematology - Hematocrit, Reticulocytes/Erythrocytes, Lymphocytes/Leukocytes, Neutrophils/Leukocytes, Basophils/Leukocytes, Eosinophils/Leukocytes and Monocytes/Leukocytes Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit

| | |
|-----------------|--|
| End point title | Change From Baseline in Hematology - Hematocrit, |
|-----------------|--|

End point description:

Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "Number of Subjects Analysed" signifies subjects evaluable for this end point and "n" signifies subjects evaluable for the each specified time point.

End point type Secondary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6 and follow up visit (28 days after last dose of study drug = maximum up to Day 71)

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|--|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 35 | 33 | 34 |
| Units: Percentage of cells | | | | |
| arithmetic mean (standard deviation) | | | | |
| Hematocrit: CAW1(n=34,35,32,34,34,33,35,33) | 0.2 (± 2.51) | -0.8 (± 2.11) | -1.3 (± 2.61) | -0.4 (± 2.27) |
| Hematocrit: CAW2(n=34,33,32,34,32,30,33,30) | -0.5 (± 2.19) | -0.8 (± 2.12) | -1.8 (± 2.42) | -0.9 (± 2.32) |
| Hematocrit: CAW4(n=28,27,33,31,30,31,25,30) | 0.0 (± 2.45) | -0.8 (± 1.96) | -1.8 (± 2.06) | -0.8 (± 2.34) |
| Hematocrit:CAW6(n=29,27,31,32,31,24,32,33) | -0.6 (± 2.47) | -0.9 (± 1.93) | -1.6 (± 2.64) | -0.7 (± 2.23) |
| Hematocrit: CAFvisit(n=30,29,30,32,30,31,32,30) | 0.3 (± 2.49) | -0.7 (± 2.24) | -1.4 (± 3.05) | -0.7 (± 2.39) |
| Reticulocytes/Ery.CAW1(n=31,31,29,29,27,28,31,27) | 0.03 (± 0.317) | 0.14 (± 0.378) | 0.02 (± 0.483) | 0.06 (± 0.364) |
| Reticulocytes/Ery.CAW2(n=31,30,29,29,25,26,29,24) | -0.03 (± 0.382) | 0.17 (± 0.325) | 0.09 (± 0.413) | -0.02 (± 0.473) |
| Reticulocytes/Ery.CAW4(n=25,24,30,27,25,23,26,23) | 0.16 (± 0.596) | -0.08 (± 0.359) | 0.01 (± 0.460) | 0.19 (± 0.429) |
| Reticulocytes/Ery.CAW6(n=26,25,28,28,24,22,28,26) | -0.06 (± 0.382) | 0.02 (± 0.361) | 0.02 (± 0.473) | 0.01 (± 0.486) |
| Ret./Ery.CAFvisit(n=27,25,27,27,23,27,27,23) | -0.11 (± 0.396) | -0.02 (± 0.384) | 0.10 (± 0.435) | -0.10 (± 0.398) |
| Lym./Leuk.CAW1(n=34,35,32,34,34,33,35,34) | -0.43 (± 6.772) | 0.68 (± 5.814) | 2.33 (± 5.616) | 0.06 (± 4.765) |
| Lym./Leukocytes:CAW2(n=34,33,32,34,32,30,33,31) | 0.20 (± 6.175) | 0.84 (± 7.544) | 1.68 (± 5.208) | 1.50 (± 5.639) |
| Lym./Leukocytes:CAW4(n=28,27,33,31,32,25,20,30) | 1.58 (± 7.591) | 0.51 (± 7.297) | 1.43 (± 5.298) | 0.43 (± 7.586) |
| Lym./Leukocytes:CAW6(n=29,27,31,32,31,24,32,33) | -0.92 (± 6.701) | -0.06 (± 5.461) | 0.82 (± 6.685) | 1.28 (± 5.881) |
| Lym./Leuk.:CAFvisit(n=30,29,30,32,30,31,32,30) | 1.53 (± 6.219) | 1.25 (± 4.974) | 1.61 (± 6.597) | -0.85 (± 6.367) |
| Neu./Leukocytes:CAW1(n=34,35,32,34,34,33,35,34) | 0.57 (± 7.515) | -0.95 (± 6.957) | -2.93 (± 6.191) | 0.30 (± 5.755) |
| Neu./Leukocytes:CAW2(n=34,33,32,34,32,30,33,31) | -0.12 (± 7.827) | -0.34 (± 8.219) | -1.70 (± 6.037) | -1.50 (± 6.578) |
| Neu./Leukocytes:CAW4(n=28,27,33,31,32,25,30,30) | -1.42 (± 8.812) | -0.30 (± 7.754) | -1.52 (± 6.661) | 0.06 (± 8.536) |

| | | | | |
|--|-----------------|-----------------|-----------------|-----------------|
| Neu./Leukocytes:CAW6(n=29,27,31,32,31,24,32,33) | 0.95 (± 8.648) | -0.58 (± 7.009) | -0.64 (± 6.833) | -1.14 (± 6.872) |
| Neu./Leuk:CAFvisit(n=30,29,30,32,30,31,32,30) | -1.71 (± 7.046) | -0.65 (± 6.057) | -1.86 (± 6.892) | 1.32 (± 7.355) |
| Bas./Leukocytes:CAW1(n=34,35,32,34,34,33,35,34) | -0.06 (± 0.431) | -0.02 (± 0.690) | -0.06 (± 0.524) | 0.08 (± 0.319) |
| Bas./Leukocytes:CAW2(n=34,33,32,34,32,30,33,31) | -0.02 (± 0.304) | 0.01 (± 0.493) | -0.09 (± 0.342) | 0.02 (± 0.323) |
| Bas./Leukocytes:CAW2(n=28,27,33,31,32,25,30,30) | -0.07 (± 0.485) | 0.06 (± 0.651) | -0.03 (± 0.420) | 0.01 (± 0.402) |
| Bas./Leukocytes:CAW6(n=29,27,31,32,31,24,32,33) | -0.07 (± 0.272) | 0.11 (± 0.809) | -0.12 (± 0.480) | 0.08 (± 0.458) |
| Bas./Leuk.:CAF visit(n=30,29,30,32,30,31,32,30) | -0.04 (± 0.360) | -0.15 (± 0.476) | -0.13 (± 0.443) | 0.02 (± 0.512) |
| Eos./Leukocytes:CAW1(n=34,35,32,34,34,33,35,34) | -0.09 (± 1.390) | 0.17 (± 1.840) | 0.17 (± 0.934) | -0.37 (± 1.549) |
| Eos./Leukocytes:CAW2(n=34,33,32,34,32,30,33,32) | -0.11 (± 1.801) | -0.20 (± 1.298) | -0.16 (± 1.284) | 0.11 (± 1.460) |
| Eos./Leukocytes:CAW4(n=28,27,33,31,32,25,30,31) | 0.42 (± 1.982) | -0.12 (± 1.725) | 0.15 (± 1.884) | -0.37 (± 1.729) |
| Eos./Leukocytes:CAW6(n=29,27,27,31,32,31,24,32,33) | -0.03 (± 1.522) | 0.22 (± 1.570) | -0.04 (± 1.213) | 0.02 (± 2.126) |
| Eos./Leuk:CAFvisit(n=30,29,30,32,30,31,32,30) | 0.16 (± 1.754) | -0.24 (± 1.860) | -0.09 (± 1.155) | -0.41 (± 2.188) |
| Mon/Leukocytes:CAW1(n=34,35,32,34,34,33,35,34) | 0.02 (± 1.913) | 0.12 (± 1.391) | 0.50 (± 1.428) | -0.06 (± 1.409) |
| Mon/Leukocytes:CAW2(n=34,33,32,34,32,30,33,31) | 0.04 (± 2.055) | -0.31 (± 1.502) | 0.30 (± 1.522) | -0.13 (± 1.267) |
| Mon/Leukocytes:CAW4(n=28,27,33,31,32,25,30,30) | -0.51 (± 2.509) | -0.17 (± 1.966) | -0.02 (± 2.072) | -0.10 (± 1.582) |
| Mon/Leukocytes:CAW6(n=29,27,31,32,31,24,32,33) | 0.06 (± 2.488) | 0.33 (± 2.257) | -0.00 (± 1.813) | -0.24 (± 1.217) |
| Mon/Leuk:CAW visit(n=30,29,30,32,30,31,32,30) | 0.06 (± 2.105) | -0.22 (± 1.304) | 0.50 (± 1.463) | -0.07 (± 1.226) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|--|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 33 | 35 | 34 |
| Units: Percentage of cells | | | | |
| arithmetic mean (standard deviation) | | | | |
| Hematocrit: CAW1(n=34,35,32,34,34,33,35,33) | -0.8 (± 2.41) | -0.5 (± 1.97) | -0.9 (± 2.04) | -0.9 (± 2.30) |
| Hematocrit: CAW2(n=34,33,32,34,32,30,33,30) | -0.7 (± 2.58) | -0.9 (± 2.55) | -0.7 (± 2.24) | -1.0 (± 2.61) |
| Hematocrit: CAW4(n=28,27,33,31,30,31,25,30) | 0.0 (± 2.73) | -1.0 (± 2.34) | -0.9 (± 2.29) | -0.5 (± 2.56) |
| Hematocrit:CAW6(n=29,27,31,32,31,24,32,33) | -0.6 (± 2.51) | -1.1 (± 1.98) | -1.1 (± 2.84) | -0.8 (± 2.60) |
| Hematocrit: CAFvisit(n=30,29,30,32,30,31,32,30) | -0.2 (± 2.50) | -0.6 (± 2.20) | -0.6 (± 2.73) | -0.3 (± 2.78) |
| Reticulocytes/Ery.CAW1(n=31,31,29,29,27,28,31,27) | 0.11 (± 0.318) | 0.01 (± 0.320) | 0.04 (± 0.355) | 0.01 (± 0.329) |
| Reticulocytes/Ery.CAW2(n=31,30,29,29,25,26,29,24) | 0.19 (± 0.443) | -0.10 (± 0.318) | 0.06 (± 0.315) | -0.01 (± 0.389) |
| Reticulocytes/Ery.CAW4(n=25,24,30,27,25,23,26,23) | 0.10 (± 0.409) | 0.03 (± 0.290) | 0.04 (± 0.446) | 0.05 (± 0.374) |

| | | | | |
|--|-----------------|-----------------|-----------------|-----------------|
| Reticulocytes/Ery.CAW6(n=26,25,28,28,24,22,28,26) | 0.15 (± 0.399) | -0.15 (± 0.310) | -0.01 (± 0.355) | 0.01 (± 0.463) |
| Ret./Ery.CAFvisit(n=27,25,27, 27, 23, 27, 27, 23) | -0.03 (± 0.298) | -0.09 (± 0.331) | -0.19 (± 0.395) | 0.11 (± 0.448) |
| Lym./Leuk.CAW1(n=34,35,32,34,3433,35, 34) | 1.31 (± 6.259) | 0.59 (± 5.179) | 0.49 (± 5.509) | 1.79 (± 6.269) |
| Lym./Leukocytes:CAW2(n=34,33,32,34,32,30,33,31) | 0.23 (± 6.175) | 0.50 (± 5.405) | 0.72 (± 6.638) | 0.86 (± 7.264) |
| Lym./Leukocytes:CAW4(n=28,27,33,31,32,25,20,30) | 2.41 (± 6.577) | -1.38 (± 5.415) | 1.07 (± 5.739) | 0.56 (± 7.264) |
| Lym./Leukocytes:CAW6(n=29,27,31,32,31,24,32,33) | 1.65 (± 5.818) | 0.50 (± 4.452) | -0.04 (± 5.300) | 1.52 (± 7.266) |
| Lym./Leuk.:CAFvisit(n=30,29,30,32,30,31,32,30) | 1.34 (± 6.165) | 0.22 (± 6.315) | 0.07 (± 5.103) | 2.48 (± 6.914) |
| Neu./Leukocytes:CAW1(n=34,35,32,34,34,33,35,34) | -0.96 (± 7.843) | -0.17 (± 5.769) | -1.87 (± 6.873) | -1.44 (± 6.580) |
| Neu./Leukocytes:CAW2(n=34,33,32,34,32,30,33,31) | -0.24 (± 6.146) | -0.49 (± 6.665) | -1.04 (± 7.376) | -0.56 (± 8.017) |
| Neu./Leukocytes:CAW4(n=28,27,33,31,32,25,30,30) | -2.25 (± 7.468) | 1.65 (± 6.622) | -1.42 (± 6.498) | -0.45 (± 7.362) |
| Neu./Leukocytes:CAW6(n=29,27,31,32,31,24,32,33) | -1.15 (± 6.969) | -0.56 (± 5.699) | 0.13 (± 6.029) | -1.01 (± 8.445) |
| Neu./Leuk:CAFvisit(n=30,29,30,32,30,31,32,30) | -1.32 (± 6.559) | -0.41 (± 6.961) | -0.71 (± 6.590) | -2.04 (± 7.700) |
| Bas./Leukocytes:CAW1(n=34,35,32,34,34,33,35,34) | 0.03 (± 0.515) | -0.03 (± 0.291) | -0.01 (± 0.411) | -0.01 (± 0.570) |
| Bas/Leukocytes:CAW2(n=34,33,32,34,32,30,33,31) | -0.03 (± 0.532) | 0.03 (± 0.355) | -0.06 (± 0.624) | -0.24 (± 0.709) |
| Bas./Leukocytes:CAW2(n=28,27,33,31,32,25,30,30) | -0.08 (± 0.712) | -0.05 (± 0.362) | -0.01 (± 0.465) | -0.10 (± 0.464) |
| Bas./Leukocytes:CAW6(n=29,27,31,32,31,24,32,33) | -0.16 (± 0.557) | -0.05 (± 0.296) | -0.12 (± 0.576) | -0.17 (± 0.750) |
| Bas./Leuk.:CAFvisit(n=30,29,30,32,30,31,32,30) | -0.25 (± 0.541) | -0.05 (± 0.449) | 0.01 (± 0.472) | -0.25 (± 0.572) |
| Eos./Leukocytes:CAW1(n=34,35,32,34,34,33,35,34) | -0.31 (± 1.607) | -0.19 (± 1.410) | 0.89 (± 1.850) | -0.23 (± 1.339) |
| Eos./Leukocytes:CAW2(n=34,33,32,34,32,30,33,32) | -0.27 (± 1.131) | -0.14 (± 1.199) | 0.16 (± 1.304) | -0.05 (± 1.531) |
| Eos./Leukocytes:CAW4(n=28,27,33,31,32,25,30,31) | -0.35 (± 1.431) | -0.34 (± 1.258) | 0.40 (± 1.468) | -0.37 (± 1.747) |
| Eos./Leukocytes:CAW6(n=29,27,27,31,32,31,24,32,33) | -0.15 (± 1.714) | -0.01 (± 1.767) | 0.05 (± 1.229) | -0.19 (± 1.840) |
| Eos./Leuk:CAFvisit(n=30,29,30,32,30,31,32,30) | 0.12 (± 1.954) | -0.05 (± 2.805) | 0.50 (± 1.986) | -0.13 (± 2.021) |
| Mon/Leukocytes:CAW1(n=34,35,32,34,34,33,35,34) | -0.01 (± 1.593) | -0.19 (± 1.043) | 0.51 (± 1.275) | -0.11 (± 1.251) |
| Mon/Leukocytes:CAW2(n=34,33,32,34,32,30,33,31) | 0.38 (± 1.362) | 0.11 (± 1.318) | 0.22 (± 1.414) | -0.01 (± 1.755) |
| Mon/Leukocytes:CAW4(n=28,27,33,31,32,25,30,30) | 0.22 (± 1.323) | 0.14 (± 1.323) | -0.03 (± 1.039) | 0.33 (± 1.695) |
| Mon/Leukocytes:CAW6(n=29,27,31,32,31,24,32,33) | -0.12 (± 1.030) | 0.13 (± 0.807) | -0.02 (± 1.324) | -0.16 (± 1.516) |
| Mon/Leuk:CAWvisit(n=30,29,30,32,30,31,32,30) | 0.13 (± 1.205) | 0.26 (± 1.543) | 0.15 (± 1.599) | -0.04 (± 1.047) |

Statistical analyses

Secondary: Change From Baseline in Hematology- Erythrocytes and Reticulocytes Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit

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|---|--|
| End point title | Change From Baseline in Hematology- Erythrocytes and Reticulocytes Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit |
| End point description: | |
| Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "Number of Subjects Analysed" signifies subjects evaluable for this end point and "n" signifies subjects evaluable for the each specified time point. | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Weeks 1, 2, 4, 6 and follow up visit (28 days after last dose of study drug = maximum up to Day 71) | |

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|--|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 35 | 33 | 34 |
| Units: 10 ¹² *cells per litre | | | | |
| arithmetic mean (standard deviation) | | | | |
| Erythrocytes: CAW1(n=34,35,32,34,34,33,35,34) | 0.03 (± 0.261) | -0.07 (± 0.232) | -0.12 (± 0.264) | -0.04 (± 0.252) |
| Erythrocytes:CAW2(n=34,33,32,34,32,30,33,31) | -0.05 (± 0.234) | -0.03 (± 0.212) | -0.18 (± 0.251) | -0.10 (± 0.208) |
| Erythrocytes:CAW4(n=28,27,33,31,32,25,30,30) | -0.01 (± 0.216) | -0.05 (± 0.221) | -0.16 (± 0.251) | -0.10 (± 0.233) |
| Erythrocytes:CAW6(n=29,27,31,32,31,24,32,33) | -0.04 (± 0.247) | -0.01 (± 0.180) | -0.17 (± 0.265) | -0.04 (± 0.238) |
| Erythrocytes:CAW visit(n=30,29,30,32,30,31,32,30) | 0.03 (± 0.220) | 0.02 (± 0.244) | -0.15 (± 0.266) | -0.03 (± 0.254) |
| Reticulocytes:CAW1(n=31,31,29,29,27,28,31,27) | 0.0 (± 0.02) | 0.0 (± 0.02) | -0.0 (± 0.02) | 0.0 (± 0.02) |
| Reticulocytes:CAW2(n=31,30,29,29,25,26,29,24) | -0.0 (± 0.02) | 0.0 (± 0.02) | 0.0 (± 0.02) | -0.0 (± 0.02) |
| Reticulocytes:CAW4(n=25,24,30,27,25,23,26,23) | 0.0 (± 0.03) | -0.0 (± 0.02) | -0.0 (± 0.02) | 0.0 (± 0.02) |
| Reticulocytes:CAW6(n=26,25,28,28,24,22,28,26) | -0.0 (± 0.02) | 0.0 (± 0.02) | 0.0 (± 0.02) | -0.0 (± 0.02) |
| Reticulocytes:CAFvisit(n=27,25,27,27,23,27,27,23) | -0.0 (± 0.02) | -0.0 (± 0.02) | 0.0 (± 0.02) | -0.0 (± 0.02) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|--|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 33 | 35 | 34 |
| Units: 10 ¹² *cells per litre | | | | |
| arithmetic mean (standard deviation) | | | | |

| | | | | |
|---|-----------------|-----------------|-----------------|-----------------|
| Erythrocytes: CAW1(n=34,35,32,34,34,33,35,34) | -0.08 (± 0.254) | -0.08 (± 0.298) | -0.08 (± 0.192) | -0.09 (± 0.240) |
| Erythrocytes:CAW2(n=34,33,32,34,32,30,33,31) | -0.07 (± 0.242) | -0.10 (± 0.366) | -0.06 (± 0.229) | -0.11 (± 0.232) |
| Erythrocytes:CAW4(n=28,27,33,31,32,25,30,30) | 0.01 (± 0.275) | -0.12 (± 0.271) | -0.08 (± 0.248) | -0.06 (± 0.219) |
| Erythrocytes:CAW6(n=29,27,31,32,31,24,32,33) | -0.02 (± 0.262) | -0.10 (± 0.256) | -0.07 (± 0.303) | -0.08 (± 0.239) |
| Erythrocytes:CAW visit(n=30,29,30,32,30,31,32,30) | 0.04 (± 0.300) | -0.08 (± 0.280) | -0.03 (± 0.308) | -0.05 (± 0.262) |
| Reticulocytes:CAW1(n=31,31,29,29,27,28,31,27) | 0.0 (± 0.02) | 0.0 (± 0.01) | 0.0 (± 0.02) | -0.0 (± 0.02) |
| Reticulocytes:CAW2(n=31,30,29,29,25,26,29,24) | 0.0 (± 0.02) | -0.0 (± 0.02) | 0.0 (± 0.02) | -0.0 (± 0.02) |
| Reticulocytes:CAW4(n=25,24,30,27,25,23,26,23) | 0.0 (± 0.02) | -0.0 (± 0.01) | -0.0 (± 0.02) | 0.0 (± 0.02) |
| Reticulocytes:CAW6(n=26,25,28,28,24,22,28,26) | 0.0 (± 0.02) | -0.0 (± 0.01) | -0.0 (± 0.02) | 0.0 (± 0.02) |
| Reticulocytes:CAFvisit(n=27,25,27,27,23,27,27,23) | -0.0 (± 0.01) | -0.0 (± 0.02) | -0.0 (± 0.02) | 0.0 (± 0.02) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hematology- Platelets, Leukocytes, Lymphocytes, Neutrophils, Basophils, Eosinophils and Monocytes Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit

| | |
|-----------------|---|
| End point title | Change From Baseline in Hematology- Platelets, Leukocytes, Lymphocytes, Neutrophils, Basophils, Eosinophils and Monocytes Laboratory Values at Weeks 1, 2, 4, 6 and Follow-up Visit |
|-----------------|---|

End point description:

Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "Number of Subjects Analysed" signifies subjects evaluable for this end point and "n" signifies subjects evaluable for the each specified time point.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Weeks 1, 2, 4, 6 and follow up visit (28 days after last dose of study drug = maximum up to Day 71)

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|---|-------------------------------|---------------------------|---------------------------|---------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 35 | 33 | 34 |
| Units: 10 ⁹ *cells per litre | | | | |
| arithmetic mean (standard deviation) | | | | |
| Platelets:CAW1(n=34,25,32,34,34,33,35,34) | 0.9 (± 60.03) | 6.8 (± 34.08) | -3.3 (± 32.39) | 1.0 (± 25.76) |
| Platelets:CAW2(n=34,33,32,34,32,30,33,31) | -4.9 (± 58.16) | 7.1 (± 43.34) | -8.1 (± 41.92) | -0.1 (± 32.45) |

| | | | | |
|---|-------------------|-------------------|-------------------|-------------------|
| Platelets:CAW4(n=28,27,33,31,32,25,30,30) | 10.5 (± 36.42) | 10.1 (± 37.55) | -2.4 (± 37.68) | -0.3 (± 36.27) |
| Platelets:CAW6(n=29,27,31,32,31,24,32,33) | 4.9 (± 35.17) | -3.3 (± 32.76) | -6.6 (± 41.66) | -2.3 (± 32.70) |
| Platelets:CAFvisit(n=29,29,30,32,30,31,32,30) | 1.3 (± 30.48) | 16.3 (± 37.13) | -8.5 (± 30.15) | 0.1 (± 32.36) |
| Leukocytes:CAW1(n=34,35,32,34,34,33,35,34) | 0.027 (± 1.8740) | 0.395 (± 1.0940) | -0.051 (± 1.2403) | 0.407 (± 1.2225) |
| Leukocytes:CAW2(n=34,33,32,34,32,30,33,31) | -0.206 (± 1.8886) | 0.459 (± 1.5567) | -0.288 (± 1.6842) | -0.094 (± 1.2877) |
| Leukocytes:CAW4(n=28,27,33,31,32,25,30,30) | -0.203 (± 1.7390) | 0.729 (± 1.3199) | 0.189 (± 1.3534) | 0.085 (± 1.3541) |
| Leukocytes:CAW6(n=29,27,31,32,31,24,32,33) | 0.160 (± 1.7059) | 0.066 (± 1.0672) | -0.505 (± 1.6474) | 0.237 (± 1.4501) |
| Leukocytes:CAFvisit(n=30,29,30,32,30,31,32,30) | -0.066 (± 1.5744) | 0.479 (± 1.0939) | -0.048 (± 2.0206) | 0.329 (± 1.3938) |
| Lymphocytes:CAW1(n=34,35,32,34,34,33,35,34) | -0.008 (± 0.5539) | 0.124 (± 0.3659) | 0.107 (± 0.3130) | 0.081 (± 0.3839) |
| Lymphocytes:CAW2(n=34,33,32,34,32,30,33,31) | -0.061 (± 0.5558) | 0.145 (± 0.3735) | 0.010 (± 0.4115) | 0.044 (± 0.4225) |
| Lymphocytes:CAW4(n=28,27,33,31,32,25,30,30) | 0.107 (± 0.4302) | 0.229 (± 0.3998) | 0.135 (± 0.4400) | 0.012 (± 0.4596) |
| Lymphocytes:CAW6(n=29,27,31,32,31,24,32,33) | 0.033 (± 0.3375) | 0.016 (± 0.3437) | -0.079 (± 0.4826) | 0.104 (± 0.4337) |
| LymphocytesCAFvisit(n=30,29,30,32,30,31,32,30) | 0.134 (± 0.3256) | 0.194 (± 0.3533) | 0.065 (± 0.6042) | -0.022 (± 0.4419) |
| Neutrophils:CAW1(n=34,35,32,34,34,33,35,34) | 0.027 (± 1.6137) | 0.205 (± 0.9185) | -0.177 (± 1.0805) | 0.319 (± 1.0276) |
| Neutrophils:CAW2(n=34,33,32,34,32,30,33,31) | -0.119 (± 1.5672) | 0.293 (± 1.5459) | -0.261 (± 1.3969) | -0.136 (± 1.0669) |
| Neutrophils:CAW4(n=28,27,33,31,32,25,30,30) | -0.304 (± 1.6117) | 0.441 (± 1.2814) | 0.036 (± 1.1595) | 0.096 (± 1.3199) |
| Neutrophils:CAW6(n=29,27,31,32,31,24,32,33) | 0.112 (± 1.6282) | -0.001 (± 0.8996) | -0.362 (± 1.3154) | 0.112 (± 1.2240) |
| Neutrophils:CAFvisit(n=30,29,30,32,30,31,32,30) | -0.229 (± 1.3379) | 0.261 (± 0.8874) | -0.114 (± 1.4545) | 0.343 (± 1.3049) |
| Basophils:CAW1(n=34,35,32,34,34,33,35,34) | -0.006 (± 0.0319) | 0.004 (± 0.0445) | -0.007 (± 0.0349) | 0.010 (± 0.0258) |
| Basophils:CAW2(n=34,33,32,34,32,30,33,31) | -0.002 (± 0.0179) | 0.004 (± 0.0261) | -0.009 (± 0.0276) | 0.001 (± 0.0197) |
| Basophils:CAW4(n=28,27,33,31,32,25,30,30) | -0.006 (± 0.0328) | 0.011 (± 0.0404) | -0.002 (± 0.0300) | 0.001 (± 0.0256) |
| Basophils:CAW6(n=29,27,31,32,31,24,32,33) | -0.005 (± 0.0186) | 0.009 (± 0.0489) | -0.012 (± 0.0313) | 0.008 (± 0.0344) |
| Basophils:CAFvisit(n=30,29,30,32,30,31,32,30) | -0.004 (± 0.0265) | -0.003 (± 0.0259) | -0.007 (± 0.0321) | 0.007 (± 0.0407) |
| Eosinophils:CAW1(n=34,35,32,34,34,33,35,34) | 0.007 (± 0.0964) | 0.036 (± 0.0963) | -0.004 (± 0.1092) | -0.011 (± 0.0930) |
| Eosinophils:CAW2(n=34,33,32,34,32,30,33,31) | -0.019 (± 0.1087) | -0.000 (± 0.0734) | -0.023 (± 0.0809) | 0.009 (± 0.0980) |
| Eosinophils:CAW4(n=28,27,33,31,32,25,30,30) | 0.032 (± 0.1813) | 0.018 (± 0.1120) | 0.008 (± 0.1325) | -0.019 (± 0.1102) |
| Eosinophils:CAW6(n=29,27,31,32,31,24,32,33) | 0.002 (± 0.0935) | 0.029 (± 0.1090) | -0.025 (± 0.1351) | 0.018 (± 0.1387) |
| Eosinophils:CAFvisit(n=30,29,30,32,30,31,32,30) | 0.022 (± 0.1461) | 0.006 (± 0.0931) | -0.023 (± 0.1196) | -0.004 (± 0.1810) |
| Monocytes:CAW1(n=34,35,32,34,34,33,35,34) | 0.006 (± 0.1796) | 0.030 (± 0.0855) | 0.030 (± 0.0987) | 0.009 (± 0.0879) |
| Monocytes:CAW2(n=34,33,32,34,32,30,33,31) | -0.006 (± 0.1509) | 0.016 (± 0.1343) | -0.003 (± 0.0724) | -0.014 (± 0.1055) |
| Monocytes:CAW4(n=28,27,33,31,32,25,30,30) | -0.035 (± 0.1904) | 0.030 (± 0.1212) | 0.013 (± 0.1234) | -0.003 (± 0.1092) |

| | | | | |
|--|------------------|------------------|-------------------|-------------------|
| Monocytes:CAW6(n=29,27,31,32,31,24,32,33) | 0.017 (± 0.1777) | 0.017 (± 0.1069) | -0.025 (± 0.1191) | -0.005 (± 0.1021) |
| Monocytes:CAF visit(n=30,29,30,32,30,31,32,30) | 0.011 (± 0.1806) | 0.021 (± 0.0824) | 0.030 (± 0.1467) | 0.005 (± 0.0887) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|---|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 33 | 35 | 34 |
| Units: 10 ⁹ *cells per litre | | | | |
| arithmetic mean (standard deviation) | | | | |
| Platelets:CAW1(n=34,25,32,34,34,33,35,34) | 8.5 (± 41.61) | 6.6 (± 33.40) | -2.1 (± 31.94) | 12.6 (± 44.08) |
| Platelets:CAW2(n=34,33,32,34,32,30,33,31) | 5.0 (± 31.39) | -4.9 (± 31.84) | 7.5 (± 37.94) | 14.8 (± 50.99) |
| Platelets:CAW4(n=28,27,33,31,32,25,30,30) | -5.9 (± 37.47) | 4.4 (± 37.79) | 0.7 (± 36.51) | 11.0 (± 46.26) |
| Platelets:CAW6(n=29,27,31,32,31,24,32,33) | -5.2 (± 38.53) | 0.2 (± 37.28) | -1.8 (± 37.05) | 8.6 (± 47.85) |
| Platelets:CAFvisit(n=29,29,30,32,30,31,32,30) | 10.2 (± 47.30) | -5.2 (± 40.70) | 5.8 (± 48.55) | 2.5 (± 58.75) |
| Leukocytes:CAW1(n=34,35,32,34,34,33,35,34) | 0.259 (± 1.1290) | 0.068 (± 1.2929) | 0.238 (± 1.4993) | -0.025 (± 2.3529) |
| Leukocytes:CAW2(n=34,33,32,34,32,30,33,31) | -0.116 (± 1.0364) | -0.007 (± 1.2637) | 0.422 (± 1.8986) | -0.006 (± 2.3428) |
| Leukocytes:CAW4(n=28,27,33,31,32,25,30,30) | -0.074 (± 1.0641) | 0.398 (± 1.5999) | 0.168 (± 1.0902) | 0.041 (± 2.1647) |
| Leukocytes:CAW6(n=29,27,31,32,31,24,32,33) | -0.244 (± 1.2763) | -0.269 (± 1.0761) | -0.048 (± 1.3823) | -0.347 (± 2.1442) |
| Leukocytes:CAFvisit(n=30,29,30,32,30,31,32,30) | 0.123 (± 0.8496) | -0.117 (± 1.4856) | 0.210 (± 1.7456) | -0.404 (± 2.4817) |
| Lymphocytes:CAW1(n=34,35,32,34,34,33,35,34) | 0.186 (± 0.3840) | 0.051 (± 0.3557) | 0.089 (± 0.4320) | 0.223 (± 0.3849) |
| Lymphocytes:CAW2(n=34,33,32,34,32,30,33,31) | 0.012 (± 0.4251) | -0.003 (± 0.3165) | 0.070 (± 0.4603) | 0.169 (± 0.5319) |
| Lymphocytes:CAW4(n=28,27,33,31,32,25,30,30) | 0.139 (± 0.3977) | 0.039 (± 0.4169) | 0.127 (± 0.2630) | 0.176 (± 0.6274) |
| Lymphocytes:CAW6(n=29,27,31,32,31,24,32,33) | 0.068 (± 0.3168) | -0.033 (± 0.3092) | 0.027 (± 0.2455) | 0.079 (± 0.3846) |
| LymphocytesCAFvisit(n=30,29,30,32,30,31,32,30) | 0.130 (± 0.4277) | -0.035 (± 0.4054) | 0.050 (± 0.4699) | 0.195 (± 0.4663) |
| Neutrophils:CAW1(n=34,35,32,34,34,33,35,34) | 0.069 (± 1.0706) | 0.017 (± 1.1291) | 0.030 (± 1.3015) | -0.251 (± 2.2421) |
| Neutrophils:CAW2(n=34,33,32,34,32,30,33,31) | -0.109 (± 0.9653) | -0.015 (± 1.1305) | 0.288 (± 1.7822) | -0.190 (± 2.0749) |
| Neutrophils:CAW4(n=28,27,33,31,32,25,30,30) | -0.190 (± 1.0404) | 0.338 (± 1.3577) | -0.005 (± 0.9958) | -0.158 (± 2.0005) |
| Neutrophils:CAW6(n=29,27,31,32,31,24,32,33) | -0.250 (± 1.1720) | -0.228 (± 0.9681) | -0.064 (± 1.2422) | -0.376 (± 2.1125) |
| Neutrophils:CAFvisit(n=30,29,30,32,30,31,32,30) | -0.020 (± 0.7731) | -0.093 (± 1.2340) | 0.088 (± 1.4614) | -0.562 (± 2.3227) |
| Basophils:CAW1(n=34,35,32,34,34,33,35,34) | 0.003 (± 0.0361) | 0.001 (± 0.0191) | 0.002 (± 0.0299) | 0.002 (± 0.0343) |
| Basophils:CAW2(n=34,33,32,34,32,30,33,31) | -0.005 (± 0.0394) | 0.003 (± 0.0244) | -0.003 (± 0.0433) | -0.012 (± 0.0428) |
| Basophils:CAW4(n=28,27,33,31,32,25,30,30) | -0.007 (± 0.0495) | -0.001 (± 0.0255) | -0.001 (± 0.0337) | -0.004 (± 0.0323) |

| | | | | |
|---|-------------------|-------------------|-------------------|-------------------|
| Basophils:CAW6(n=29,27,31,32,31,24,32,33) | -0.015 (± 0.0415) | -0.004 (± 0.0188) | -0.009 (± 0.0373) | -0.015 (± 0.0383) |
| Basophils:CAFvisit(n=30,29,30,32,30,31,32,30) | -0.015 (± 0.0426) | -0.005 (± 0.0269) | 0.001 (± 0.0295) | -0.019 (± 0.0361) |
| Eosinophils:CAW1(n=34,35,32,34,34,33,35,34) | -0.014 (± 0.1216) | -0.008 (± 0.1148) | 0.068 (± 0.0959) | -0.006 (± 0.1165) |
| Eosinophils:CAW2(n=34,33,32,34,32,30,33,31) | -0.029 (± 0.0915) | -0.006 (± 0.0621) | 0.022 (± 0.0762) | 0.005 (± 0.1256) |
| Eosinophils:CAW4(n=28,27,33,31,32,25,30,30) | -0.032 (± 0.1040) | -0.012 (± 0.0832) | 0.042 (± 0.1076) | -0.012 (± 0.1499) |
| Eosinophils:CAW6(n=29,27,31,32,31,24,32,33) | -0.027 (± 0.1125) | -0.007 (± 0.1025) | -0.001 (± 0.0812) | -0.022 (± 0.1415) |
| Eosinophils:CAFvisit(n=30,29,30,32,30,31,32,30) | 0.008 (± 0.1270) | -0.008 (± 0.2483) | 0.048 (± 0.1520) | -0.011 (± 0.1945) |
| Monocytes:CAW1(n=34,35,32,34,34,33,35,34) | 0.019 (± 0.1055) | 0.006 (± 0.0877) | 0.051 (± 0.1244) | 0.011 (± 0.1195) |
| Monocytes:CAW2(n=34,33,32,34,32,30,33,31) | 0.017 (± 0.0865) | 0.013 (± 0.0983) | 0.049 (± 0.1471) | 0.025 (± 0.1496) |
| Monocytes:CAW4(n=28,27,33,31,32,25,30,30) | 0.009 (± 0.0986) | 0.035 (± 0.0978) | 0.007 (± 0.1008) | 0.038 (± 0.1331) |
| Monocytes:CAW6(n=29,27,31,32,31,24,32,33) | -0.019 (± 0.0726) | 0.004 (± 0.0847) | 0.003 (± 0.1097) | -0.012 (± 0.1200) |
| Monocytes:CAF visit(n=30,29,30,32,30,31,32,30) | 0.021 (± 0.0739) | 0.018 (± 0.1047) | 0.029 (± 0.1788) | -0.006 (± 0.1282) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Lipids Profile Values at Week 6

| | |
|---|---|
| End point title | Change From Baseline in Lipids Profile Values at Week 6 |
| End point description: | |
| Lipid parameters that were assessed: high density lipoprotein (HDL) cholesterol, triglycerides, cholesterol, low density lipoprotein (LDL) cholesterol. Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "Number of Subjects Analysed" signifies subjects evaluable for this end point and "n" signifies subjects evaluable for the each specified rows. | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 6 | |

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|--|-------------------------------|---------------------------|---------------------------|---------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 28 | 27 | 31 | 32 |
| Units: Microgram per decilitre | | | | |
| arithmetic mean (standard deviation) | | | | |
| HDL cholesterol | -2.8 (± 6.65) | 0.1 (± 5.34) | -1.3 (± 7.74) | 2.7 (± 8.33) |
| Triglycerides(n=28,27,31,31,29,24,30,32) | 3.3 (± 38.84) | -4.2 (± 59.30) | -6.5 (± 37.30) | 1.8 (± 60.74) |
| Cholesterol | -3.5 (± 16.39) | -5.6 (± 27.59) | -12.8 (± 20.53) | 6.8 (± 24.09) |

| | | | | |
|-----------------|----------------|----------------|-----------------|---------------|
| LDL Cholesterol | -3.4 (± 14.45) | -6.3 (± 25.28) | -12.1 (± 16.44) | 2.1 (± 20.13) |
|-----------------|----------------|----------------|-----------------|---------------|

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|--|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 29 | 24 | 30 | 32 |
| Units: Microgram per decilitre | | | | |
| arithmetic mean (standard deviation) | | | | |
| HDL cholesterol | 1.9 (± 11.18) | 0.0 (± 6.76) | 1.2 (± 4.12) | 0.3 (± 8.56) |
| Triglycerides(n=28,27,31,31,29,24,30,32) | -18.9 (± 56.78) | -8.1 (± 50.41) | -7.0 (± 58.36) | -4.4 (± 55.66) |
| Cholesterol | -10.4 (± 30.79) | -0.2 (± 18.70) | 5.3 (± 30.58) | -0.9 (± 19.86) |
| LDL Cholesterol | -11.0 (± 29.06) | -0.8 (± 14.48) | 4.4 (± 23.55) | -1.1 (± 16.29) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ratio of LDL Cholesterol to HDL Cholesterol Lipids Profile at Week 6

| | |
|-----------------|--|
| End point title | Change From Baseline in Ratio of LDL Cholesterol to HDL Cholesterol Lipids Profile at Week 6 |
|-----------------|--|

End point description:

Mean change in total cholesterol/HDL cholesterol ratio was assessed and reported. Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "Number of Subjects Analysed" signifies subjects evaluable for this end point.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 6

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|--------------------------------------|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 28 | 27 | 31 | 32 |
| Units: Ratio | | | | |
| arithmetic mean (standard deviation) | 0.0 (± 0.31) | -0.1 (± 0.48) | -0.2 (± 0.40) | -0.0 (± 0.32) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|------------------|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
|------------------|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|

| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
|--------------------------------------|-----------------|-----------------|-----------------|-----------------|
| Number of subjects analysed | 29 | 24 | 30 | 32 |
| Units: Ratio | | | | |
| arithmetic mean (standard deviation) | -0.3 (± 0.77) | -0.0 (± 0.35) | 0.0 (± 0.46) | -0.0 (± 0.42) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Electrocardiogram (ECG) Parameter- Heart Rate at Weeks 2 and 6

| | |
|-----------------|--|
| End point title | Change From Baseline in Electrocardiogram (ECG) Parameter- Heart Rate at Weeks 2 and 6 |
|-----------------|--|

End point description:

Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "n" signifies subjects evaluable for the each specified time point.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Weeks 2 and 6

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|---|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 37 | 36 | 37 |
| Units: Beats per minute | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 66.8 (± 11.45) | 66.9 (± 9.33) | 68.4 (± 14.66) | 64.9 (± 9.05) |
| Change at week 2 (n=33,31,33,33,31,26,34,32) | 0.7 (± 10.05) | -0.5 (± 8.03) | -1.8 (± 11.53) | -0.6 (± 7.88) |
| Change at week 6 (n=28,27,33,32,30,24,31,33) | 0.3 (± 6.19) | -1.1 (± 7.65) | -1.7 (± 9.06) | 0.8 (± 8.53) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|---|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 36 | 36 | 36 | 37 |
| Units: Beats per minute | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 64.9 (± 12.26) | 66.9 (± 12.03) | 68.2 (± 12.11) | 68.1 (± 12.48) |
| Change at week 2 (n=33,31,33,33,31,26,34,32) | 1.9 (± 8.01) | 2.2 (± 8.76) | 1.7 (± 9.13) | 1.7 (± 12.52) |
| Change at week 6 (n=28,27,33,32,30,24,31,33) | -0.3 (± 8.46) | -0.8 (± 8.23) | 0.5 (± 8.76) | -0.4 (± 12.06) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PR, QRS, QTCF and QT Interval at Weeks 2 and 6

| | |
|---|--|
| End point title | Change From Baseline in PR, QRS, QTCF and QT Interval at Weeks 2 and 6 |
| End point description: Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "n" signifies subjects evaluable for the each specified time point. | |
| End point type | Secondary |
| End point timeframe: Baseline, Weeks 2 and 6 | |

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|---|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 37 | 36 | 37 |
| Units: Milliseconds | | | | |
| arithmetic mean (standard deviation) | | | | |
| PR interval: baseline | 161.9 (± 23.30) | 160.2 (± 24.01) | 161.4 (± 27.59) | 162.5 (± 22.04) |
| PR interval:CAW2(n=33,31,33,33,31,26,34) | 0.8 (± 14.41) | -0.9 (± 15.92) | 0.7 (± 18.54) | 0.3 (± 10.13) |
| PR interval:CAW6(n=28,27,33,32,30,24,31,33) | -0.9 (± 10.16) | -0.1 (± 13.81) | 2.8 (± 19.66) | 2.9 (± 13.63) |
| QRS interval: baseline | 92.5 (± 9.36) | 91.5 (± 9.71) | 91.1 (± 9.29) | 93.0 (± 11.13) |
| QRS intervalCAW2(n=33,31,33,33,31,26,34, | -1.4 (± 8.02) | -0.4 (± 5.34) | -1.3 (± 3.46) | -0.8 (± 5.64) |
| QRS interval:CAW6(n=28,27,33,32,30,24,31 | -1.9 (± 6.55) | 1.4 (± 5.62) | -0.5 (± 4.76) | -0.9 (± 4.04) |
| QTCF interval: baseline | 407.7 (± 17.78) | 397.9 (± 15.98) | 403.8 (± 22.43) | 408.5 (± 18.42) |
| QTCF interval:CAW2(n=33,31,33,33,31,26,34,32) | -5.7 (± 11.86) | -1.5 (± 13.70) | -3.9 (± 15.60) | 2.6 (± 16.20) |
| QTCF interval:CAW6(n=28,27,33,32,30,24,31 | -4.1 (± 14.61) | -0.5 (± 14.93) | -1.9 (± 14.37) | 0.3 (± 17.19) |
| QT interval: baseline | 395.2 (± 31.53) | 385.3 (± 23.64) | 388.8 (± 33.66) | 401.0 (± 25.23) |
| QT interval:CAW2(n=33,31,33,33,31,26,34,32) | -5.9 (± 23.16) | -1.3 (± 17.73) | -1.1 (± 19.31) | 3.5 (± 21.06) |
| QT interval:CAW6(n=28,27,33,32,30,24,31 | -4.9 (± 19.54) | 1.3 (± 18.11) | 0.9 (± 16.11) | -4.1 (± 23.42) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|---|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 36 | 36 | 36 | 37 |
| Units: Milliseconds | | | | |
| arithmetic mean (standard deviation) | | | | |
| PR interval: baseline | 160.7 (± 24.20) | 156.4 (± 22.65) | 157.9 (± 23.55) | 157.8 (± 23.15) |
| PR interval:CAW2(n=33,31,33,33,31,26,34) | 1.1 (± 14.42) | 6.0 (± 14.79) | 1.2 (± 16.06) | 2.1 (± 7.98) |
| PR interval:CAW6(n=28,27,33,32,30,24,31,33) | 3.5 (± 21.88) | 4.0 (± 14.56) | 6.5 (± 19.15) | 5.7 (± 16.11) |
| QRS interval: baseline | 93.1 (± 8.69) | 92.2 (± 13.00) | 92.4 (± 13.30) | 91.5 (± 11.68) |
| QRS intervalCAW2(n=33,31,33,33,31,26,34, | 0.1 (± 4.79) | 1.5 (± 9.29) | 0.2 (± 8.07) | 1.0 (± 5.63) |
| QRS interval:CAW6(n=28,27,33,32,30,24,31 | -1.3 (± 4.00) | 0.9 (± 6.37) | 0.6 (± 5.49) | 0.7 (± 5.67) |
| QTCF interval: baseline | 401.0 (± 16.29) | 403.0 (± 16.65) | 397.7 (± 17.05) | 405.0 (± 20.38) |
| QTCF interval:CAW2(n=33,31,33,33,31,26,34,32) | -0.6 (± 12.75) | 1.4 (± 15.56) | 2.4 (± 10.32) | -4.6 (± 15.43) |
| QTCF interval:CAW6(n=28,27,33,32,30,24,31 | -1.4 (± 14.93) | 4.6 (± 14.27) | 2.0 (± 11.94) | -0.2 (± 9.67) |
| QT interval: baseline | 392.0 (± 27.36) | 390.9 (± 24.87) | 383.8 (± 30.79) | 390.6 (± 32.43) |
| QT interval:CAW2(n=33,31,33,33,31,26,34,32) | -4.5 (± 15.75) | 1.2 (± 24.03) | -2.3 (± 18.69) | -4.6 (± 25.76) |
| QT interval:CAW6(n=28,27,33,32,30,24,31 | -0.9 (± 20.12) | 7.8 (± 24.11) | -1.4 (± 20.47) | 4.0 (± 27.74) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Vital Signs- Blood Pressure (BP) at Weeks 2 and 6

| | |
|---|---|
| End point title | Change From Baseline in Vital Signs- Blood Pressure (BP) at Weeks 2 and 6 |
| End point description: Blood pressure included supine and sitting systolic and diastolic BP. Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "n" signifies subjects evaluable for the each specified time point. | |
| End point type | Secondary |
| End point timeframe: Baseline, Weeks 2 and 6 | |

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|--|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 25 | 26 | 29 | 22 |
| Units: Millimeters of mercury | | | | |
| arithmetic mean (standard deviation) | | | | |
| Supine systolic BP: Baseline | 123.3 (± 12.01) | 123.2 (± 12.35) | 123.0 (± 13.89) | 119.7 (± 9.08) |
| Supine SBP:CAW2(n=21,20,25,18,20,18,21,22) | 0.3 (± 11.55) | -1.4 (± 9.61) | 0.5 (± 14.73) | 2.3 (± 6.99) |
| Supine SBP:CAW 6(n=16,15,24,17,19,18,21,22) | -0.2 (± 12.98) | 1.1 (± 10.06) | 2.0 (± 14.05) | 0.2 (± 9.13) |
| Sitting SBP: Baseline(n=15,17,17,19,19,16,18,15) | 117.7 (± 13.05) | 120.8 (± 10.26) | 120.2 (± 12.43) | 116.9 (± 17.76) |
| Sitting SBP: CAW2(n=12,11,8,15,11,7,11,10) | 1.3 (± 12.12) | -1.9 (± 11.86) | -3.9 (± 14.54) | 1.3 (± 13.59) |
| Sitting SBP: CAW6(n=12,10,9,15,10,5,10,11) | 0.6 (± 12.24) | -7.5 (± 8.67) | -9.4 (± 8.95) | 1.0 (± 14.63) |
| Supine DBP: Baseline | 77.7 (± 9.28) | 75.2 (± 8.79) | 78.8 (± 8.39) | 74.5 (± 8.26) |
| Supine DBP: CAW2(n=21,20,25,18,20,18,21,22) | 0.5 (± 7.51) | 0.6 (± 6.47) | -0.4 (± 8.50) | 1.6 (± 10.33) |
| Supine DBP: CAW 6(n=16,15,24,17,19,18,21,22) | -2.5 (± 7.69) | 1.5 (± 7.61) | -0.7 (± 8.32) | 0.5 (± 7.96) |
| Sitting DBP: Baseline | 76.5 (± 9.28) | 80.1 (± 6.76) | 77.8 (± 10.02) | 69.6 (± 11.48) |
| Sitting DBP: CAW2(n=12, 11, 8, 15, 11, 7, 11, 10) | -1.6 (± 8.49) | 0.7 (± 7.93) | 0.0 (± 9.44) | 1.6 (± 12.00) |
| Sitting DBP: CAW 6(n=12, 10, 9, 15, 10, 5, 10, 11) | 0.8 (± 9.90) | 0.0 (± 5.79) | -1.6 (± 11.97) | 1.1 (± 15.61) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|---|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 23 | 26 | 23 | 25 |
| Units: Millimeters of mercury | | | | |
| arithmetic mean (standard deviation) | | | | |
| Supine systolic BP: Baseline | 122.6 (± 12.76) | 123.1 (± 12.40) | 117.1 (± 14.07) | 118.9 (± 12.43) |
| Supine SBP:CAW2(n=21,20,25,18,20,18,21,22) | -0.3 (± 10.25) | -0.3 (± 8.02) | 3.5 (± 13.65) | 2.9 (± 8.48) |
| Supine SBP:CAW 6(n=16,15,24,17,19,18,21,22) | -3.4 (± 11.02) | -1.4 (± 10.49) | 2.1 (± 12.41) | 0.6 (± 10.31) |
| Sitting SBP: Baseline(n=15,17,17,19,19,16,18,15) | 124.6 (± 11.25) | 119.4 (± 12.96) | 122.9 (± 15.25) | 125.6 (± 12.21) |
| Sitting SBP: CAW2(n=12,11,8,15,11,7,11,10) | -2.4 (± 11.76) | -3.1 (± 10.46) | 1.1 (± 9.81) | 4.4 (± 11.68) |
| Sitting SBP: CAW6(n=12,10,9,15,10,5,10,11) | -8.4 (± 10.81) | -0.6 (± 14.40) | -3.6 (± 8.37) | -1.5 (± 5.80) |
| Supine DBP: Baseline | 75.9 (± 8.78) | 77.5 (± 8.71) | 74.4 (± 8.20) | 73.7 (± 8.59) |
| Supine DBP: CAW2(n=21,20,25,18,20,18,21,22) | 1.2 (± 8.32) | -2.8 (± 6.69) | 1.6 (± 8.89) | 1.4 (± 7.74) |
| Supine DBP: CAW 6(n=16,15,24,17,19,18,21,22) | -0.9 (± 10.65) | -1.6 (± 6.22) | 1.9 (± 9.72) | 0.5 (± 6.32) |
| Sitting DBP: Baseline | 80.9 (± 8.21) | 75.1 (± 5.77) | 77.1 (± 12.00) | 80.3 (± 7.83) |
| Sitting DBP: CAW2(n=12, 11, 8, 15, 11, 7, 11, 10) | -2.9 (± 10.77) | 1.7 (± 8.20) | 4.5 (± 5.80) | -1.2 (± 6.49) |

| | | | | |
|--|---------------|----------------|---------------|--------------|
| Sitting DBP: CAW 6(n=12, 10, 9, 15, 10, 5, 10, 11) | -5.3 (± 9.27) | -2.8 (± 12.60) | -0.3 (± 7.89) | 0.4 (± 8.41) |
|--|---------------|----------------|---------------|--------------|

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Vital Signs- Pulse Rate at Weeks 2 and 6

| | |
|-----------------|--|
| End point title | Change From Baseline in Vital Signs- Pulse Rate at Weeks 2 and 6 |
|-----------------|--|

End point description:

Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "n" signifies subjects evaluable for the each specified time point.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Weeks 2 and 6

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|--|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 37 | 36 | 37 |
| Units: Beats per minute | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 69.6 (± 12.58) | 69.5 (± 9.82) | 72.9 (± 14.30) | 67.9 (± 9.31) |
| Change at week 2(n=33,31,33,33,31,26,33,32) | 0.5 (± 10.41) | 0.2 (± 8.11) | -2.5 (± 9.66) | 1.1 (± 9.13) |
| Change at week 6(n=28,27,33,32,30,24,31,33) | 2.1 (± 10.59) | 0.3 (± 8.04) | -1.4 (± 11.90) | 0.9 (± 9.71) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|--|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 36 | 36 | 36 | 37 |
| Units: Beats per minute | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 68.8 (± 11.76) | 69.4 (± 11.15) | 70.1 (± 11.18) | 68.2 (± 9.59) |
| Change at week 2(n=33,31,33,33,31,26,33,32) | 0.5 (± 6.54) | 3.7 (± 9.47) | 2.8 (± 8.28) | 4.1 (± 9.16) |
| Change at week 6(n=28,27,33,32,30,24,31,33) | 1.8 (± 8.73) | 4.1 (± 6.76) | 0.5 (± 9.12) | 1.8 (± 8.64) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Vital Signs- Temperature at Weeks 2 and 6

| | |
|-----------------|---|
| End point title | Change From Baseline in Vital Signs- Temperature at Weeks 2 and 6 |
|-----------------|---|

End point description:

Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug. Here, "n" signifies subjects evaluable for the each specified time point.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Weeks 2 and 6

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|--|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 37 | 36 | 37 |
| Units: Degree Celsius | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 36.5 (± 0.33) | 36.5 (± 0.43) | 36.6 (± 0.44) | 36.6 (± 0.33) |
| Change at week 2(n=33,31,33,33,31,26,33,32) | -0.1 (± 0.41) | -0.1 (± 0.30) | 0.0 (± 0.38) | -0.0 (± 0.43) |
| Change at week 6(n=28,27,33,32,30,24,31,33) | -0.0 (± 0.40) | -0.0 (± 0.29) | 0.0 (± 0.38) | 0.1 (± 0.32) |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|--|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 36 | 36 | 36 | 37 |
| Units: Degree Celsius | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 36.5 (± 0.37) | 36.5 (± 0.29) | 36.6 (± 0.41) | 36.6 (± 0.29) |
| Change at week 2(n=33,31,33,33,31,26,33,32) | 0.1 (± 0.35) | -0.0 (± 0.34) | 0.0 (± 0.38) | 0.0 (± 0.41) |
| Change at week 6(n=28,27,33,32,30,24,31,33) | 0.0 (± 0.29) | 0.1 (± 0.50) | 0.0 (± 0.37) | -0.0 (± 0.46) |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Each Severity Grade in Local Tolerability Assessments

| | |
|-----------------|--|
| End point title | Number of Subjects With Each Severity Grade in Local |
|-----------------|--|

End point description:

Local tolerability skin assessments were performed by investigator and graded based on severity from grade 0 to 4 as: grade 0=none (no evidence of local intolerance); grade 1=mild (minimal erythema and/or oedema, slight glazed appearance); grade 2= moderate (definite erythema and/or oedema with peeling and/or cracking but needs no adaptation of posology) grade 3=severe (erythema, oedema glazing with fissures, few vesicles or papules consider removing topical agent [if still in place]) and grade 4= very severe (strong reaction spreading beyond the treated area, bullous reaction, erosions: removal of topical agent [if still in place]). Higher grades indicated worsening of condition. Only those categories in which at least 1 subject had data were reported. Safety analysis set included all subjects who were randomly assigned to study drug and who applied at least 1 dose of study drug.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Day 1 and any day on of Week 1, 2, 4, 6: pre dose (before application of IP) and post dose (after application of IP); Follow up visit (28 days after last dose of study drug = maximum up to Day 71) and Early termination (anytime within week 11)

| End point values | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD | PF-06700841 1.0% Cream QD |
|---------------------------------------|-------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 37 | 37 | 36 | 37 |
| Units: Subjects | | | | |
| Day 1: tolerability before: none | 35 | 35 | 31 | 33 |
| Day 1: tolerability before: mild | 0 | 0 | 1 | 3 |
| Day 1: tolerability before: moderate | 2 | 2 | 4 | 1 |
| Day 1: tolerability after: none | 33 | 36 | 30 | 33 |
| Day 1: tolerability after: mild | 1 | 0 | 1 | 2 |
| Day 1: tolerability after: moderate | 1 | 1 | 3 | 1 |
| Week 1: tolerability before: none | 31 | 28 | 28 | 30 |
| Week 1: tolerability before: mild | 1 | 2 | 3 | 3 |
| Week 1: tolerability before: moderate | 2 | 0 | 3 | 0 |
| Week 1: tolerability after: none | 28 | 29 | 29 | 30 |
| Week 1: tolerability after: mild | 2 | 2 | 2 | 3 |
| Week 1: tolerability after: moderate | 2 | 0 | 2 | 0 |
| Week 2: tolerability before: none | 29 | 28 | 26 | 30 |
| Week 2: tolerability before: mild | 3 | 2 | 2 | 2 |
| Week 2: tolerability before: moderate | 1 | 0 | 3 | 1 |
| Week 2: tolerability after: none | 28 | 26 | 29 | 31 |
| Week 2: tolerability after: mild | 1 | 3 | 2 | 1 |
| Week 2: tolerability after: moderate | 1 | 0 | 1 | 1 |
| Week 4: tolerability before: none | 27 | 26 | 30 | 30 |
| Week 4: tolerability before: mild | 0 | 2 | 2 | 2 |
| Week 4: tolerability before: moderate | 1 | 0 | 1 | 0 |
| Week 4: tolerability after: none | 24 | 26 | 30 | 30 |
| Week 4: tolerability after: mild | 1 | 2 | 2 | 1 |
| Week 4: tolerability after: moderate | 1 | 0 | 0 | 0 |
| Week 6: tolerability before: none | 26 | 25 | 29 | 30 |
| Week 6: tolerability before: mild | 1 | 1 | 2 | 1 |
| Week 6: tolerability after: none | 25 | 24 | 28 | 29 |
| Week 6: tolerability after: mild | 0 | 1 | 3 | 0 |
| Early termination: tolerability: none | 6 | 5 | 3 | 2 |

| | | | | |
|---|----|----|----|----|
| Early termination: tolerability: mild | 0 | 2 | 0 | 0 |
| Early termination: tolerability: moderate | 2 | 0 | 0 | 0 |
| Early termination: tolerability: severe | 1 | 1 | 0 | 1 |
| Follow Up: tolerability: none | 22 | 26 | 25 | 25 |
| Follow Up: tolerability: mild | 1 | 0 | 2 | 0 |
| Follow Up: tolerability: moderate | 1 | 0 | 1 | 4 |
| Follow Up: tolerability: severe | 0 | 0 | 1 | 0 |

| End point values | PF-06700841 3.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID |
|---|---------------------------------|---------------------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 36 | 36 | 36 | 37 |
| Units: Subjects | | | | |
| Day 1: tolerability before: none | 36 | 35 | 34 | 36 |
| Day 1: tolerability before: mild | 0 | 1 | 2 | 0 |
| Day 1: tolerability before: moderate | 0 | 0 | 0 | 1 |
| Day 1: tolerability after: none | 35 | 34 | 32 | 33 |
| Day 1: tolerability after: mild | 0 | 0 | 2 | 2 |
| Day 1: tolerability after: moderate | 0 | 1 | 0 | 0 |
| Week 1: tolerability before: none | 30 | 30 | 33 | 33 |
| Week 1: tolerability before: mild | 3 | 1 | 1 | 1 |
| Week 1: tolerability before: moderate | 0 | 0 | 0 | 0 |
| Week 1: tolerability after: none | 28 | 27 | 32 | 31 |
| Week 1: tolerability after: mild | 2 | 3 | 1 | 1 |
| Week 1: tolerability after: moderate | 0 | 1 | 0 | 0 |
| Week 2: tolerability before: none | 30 | 23 | 31 | 33 |
| Week 2: tolerability before: mild | 1 | 1 | 1 | 0 |
| Week 2: tolerability before: moderate | 0 | 0 | 1 | 0 |
| Week 2: tolerability after: none | 29 | 23 | 32 | 30 |
| Week 2: tolerability after: mild | 1 | 2 | 0 | 1 |
| Week 2: tolerability after: moderate | 0 | 0 | 1 | 0 |
| Week 4: tolerability before: none | 30 | 24 | 31 | 31 |
| Week 4: tolerability before: mild | 0 | 0 | 1 | 1 |
| Week 4: tolerability before: moderate | 1 | 1 | 0 | 0 |
| Week 4: tolerability after: none | 29 | 24 | 31 | 30 |
| Week 4: tolerability after: mild | 0 | 0 | 1 | 0 |
| Week 4: tolerability after: moderate | 1 | 1 | 0 | 0 |
| Week 6: tolerability before: none | 30 | 21 | 30 | 32 |
| Week 6: tolerability before: mild | 0 | 1 | 0 | 1 |
| Week 6: tolerability after: none | 29 | 22 | 30 | 30 |
| Week 6: tolerability after: mild | 0 | 0 | 0 | 0 |
| Early termination: tolerability: none | 2 | 9 | 2 | 1 |
| Early termination: tolerability: mild | 0 | 0 | 0 | 1 |
| Early termination: tolerability: moderate | 0 | 1 | 0 | 0 |
| Early termination: tolerability: severe | 1 | 0 | 0 | 0 |
| Follow Up: tolerability: none | 28 | 25 | 26 | 28 |
| Follow Up: tolerability: mild | 0 | 1 | 1 | 1 |
| Follow Up: tolerability: moderate | 1 | 1 | 0 | 0 |
| Follow Up: tolerability: severe | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline (Day 1) up to at least 28 days after last dose of study drug (approximately up to Week 11)

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 23.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------------------------------|
| Reporting group title | Vehicle Cream Once Daily (QD) |
|-----------------------|-------------------------------|

Reporting group description:

Subjects or caregivers of subjects, topically applied vehicle cream on all eligible atopic dermatitis (AD) areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|-----------------------|---------------------------|
| Reporting group title | PF-06700841 0.1% Cream QD |
|-----------------------|---------------------------|

Reporting group description:

Subjects or caregivers of subjects, topically applied of PF-06700841 0.1 percent (%) cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|-----------------------|---------------------------|
| Reporting group title | PF-06700841 0.3% Cream QD |
|-----------------------|---------------------------|

Reporting group description:

Subjects or caregivers of subjects, topically applied of PF-06700841 0.3 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|-----------------------|---------------------------|
| Reporting group title | PF-06700841 1.0% Cream QD |
|-----------------------|---------------------------|

Reporting group description:

Subjects or caregivers of subjects, topically applied of PF-06700841 1.0 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|-----------------------|---------------------------------|
| Reporting group title | Vehicle Cream Twice Daily (BID) |
|-----------------------|---------------------------------|

Reporting group description:

Subjects or caregivers of subjects, topically applied vehicle cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|-----------------------|---------------------------|
| Reporting group title | PF-06700841 3.0% Cream QD |
|-----------------------|---------------------------|

Reporting group description:

Subjects or caregivers of subjects, topically applied of PF-06700841 3.0 % cream on all eligible AD areas (of subjects) once daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|-----------------------|----------------------------|
| Reporting group title | PF-06700841 0.3% Cream BID |
|-----------------------|----------------------------|

Reporting group description:

Subjects or caregivers of subjects, topically applied PF-06700841 0.3% cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| | |
|-----------------------|----------------------------|
| Reporting group title | PF-06700841 1.0% Cream BID |
|-----------------------|----------------------------|

Reporting group description:

Subjects or caregivers of subjects, topically applied PF-06700841 1.0% cream on all eligible AD areas (of subjects) twice daily for a maximum of 6 weeks. Eligibility of AD areas to be treated were determined on Day 1 by investigator. Subjects were followed up for 4 weeks after last dose.

| Serious adverse events | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD |
|---|-------------------------------|---------------------------|---------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

| Serious adverse events | PF-06700841 1.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 3.0% Cream QD |
|---|---------------------------|---------------------------------|---------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

| Serious adverse events | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID | |
|---|----------------------------|----------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | Vehicle Cream Once Daily (QD) | PF-06700841 0.1% Cream QD | PF-06700841 0.3% Cream QD |
|---|-------------------------------|---------------------------|---------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 18 / 37 (48.65%) | 17 / 37 (45.95%) | 11 / 36 (30.56%) |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Pregnancy | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Application site erythema | | | |

| | | | |
|--------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Application site pruritus | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Administration site warmth | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Application site acne | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Application site pain | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 37 (2.70%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Injection site pain | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 1 | 0 | 1 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vessel puncture site haematoma | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 37 (2.70%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Immune system disorders | | | |
| Allergy to arthropod sting | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|---------------------|---------------------|---------------------|
| Cockroach allergy subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Mite allergy subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Allergy to animal subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Reproductive system and breast disorders Menstruation irregular subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 1 / 37 (2.70%) 1 | 0 / 36 (0.00%) 0 |
| Metrorrhagia subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 37 (0.00%) 0 | 2 / 36 (5.56%) 2 |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 1 / 37 (2.70%) 1 | 2 / 37 (5.41%) 2 | 1 / 36 (2.78%) 1 |
| Increased viscosity of bronchial secretion subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 1 / 37 (2.70%) 1 | 0 / 36 (0.00%) 0 |
| Psychiatric disorders Insomnia subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 37 (0.00%) 0 | 1 / 36 (2.78%) 1 |
| Aspartate aminotransferase increased | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 37 (2.70%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 1 | 1 |
| Blood glucose increased | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Electrocardiogram T wave inversion | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 37 (2.70%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Glomerular filtration rate decreased | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lipids abnormal | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 37 (2.70%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Pregnancy test positive | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Limb injury | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 1 / 37 (2.70%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Tooth fracture | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| Burning sensation subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 1 / 37 (2.70%) 1 | 0 / 36 (0.00%) 0 |
| Headache subjects affected / exposed occurrences (all) | 1 / 37 (2.70%) 1 | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Eye disorders | | | |
| Swelling of eyelid subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Ulcerative keratitis subjects affected / exposed occurrences (all) | 1 / 37 (2.70%) 1 | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Dyspepsia subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Nausea subjects affected / exposed occurrences (all) | 1 / 37 (2.70%) 1 | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis atopic subjects affected / exposed occurrences (all) | 3 / 37 (8.11%) 3 | 3 / 37 (8.11%) 3 | 1 / 36 (2.78%) 1 |
| Pruritus subjects affected / exposed occurrences (all) | 2 / 37 (5.41%) 3 | 1 / 37 (2.70%) 1 | 0 / 36 (0.00%) 0 |
| Acne subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 1 / 37 (2.70%) 1 | 0 / 36 (0.00%) 0 |
| Dermatitis contact subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Dry skin subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Eczema | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 1 / 37 (2.70%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Granuloma annulare | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photosensitivity reaction | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin discolouration | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin irritation | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Solar urticaria | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Dysuria | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal and connective tissue disorders | | | |
| Back pain | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Infections and infestations | | | |
| Influenza | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 37 (2.70%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 2 / 37 (5.41%) | 2 / 36 (5.56%) |
| occurrences (all) | 1 | 2 | 2 |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 2 / 36 (5.56%) |
| occurrences (all) | 2 | 0 | 2 |
| Bacterial allergy | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema infected | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Furuncle | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|-----------------------------------|----------------|----------------|----------------|
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 37 (2.70%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 37 (2.70%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Kaposi's varicelliform eruption | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 37 (2.70%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Staphylococcal skin infection | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 37 (2.70%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 1 | 1 |

| | | | |
|---|----------------|----------------|----------------|
| Vaginal infection | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral pharyngitis | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 37 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Viral rhinitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 37 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |

| Non-serious adverse events | PF-06700841 1.0% Cream QD | Vehicle Cream Twice Daily (BID) | PF-06700841 3.0% Cream QD |
|---|------------------------------|------------------------------------|------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 12 / 37 (32.43%) | 17 / 36 (47.22%) | 10 / 36 (27.78%) |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Pregnancy | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| General disorders and administration site conditions | | | |
| Application site erythema | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 2 / 36 (5.56%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Application site pruritus | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 3 / 36 (8.33%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Administration site warmth | | | |

| | | | |
|--------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Application site acne | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Application site pain | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 36 (2.78%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 1 | 1 |
| Chills | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 36 (2.78%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 1 | 1 |
| Vessel puncture site haematoma | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| Allergy to arthropod sting | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 36 (2.78%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cockroach allergy | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 36 (2.78%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mite allergy | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 36 (2.78%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|--|---------------------|---------------------|---------------------|
| Allergy to animal subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 1 / 36 (2.78%) 1 | 0 / 36 (0.00%) 0 |
| Reproductive system and breast disorders | | | |
| Menstruation irregular subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Metrorrhagia subjects affected / exposed occurrences (all) | 1 / 37 (2.70%) 1 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 1 / 36 (2.78%) 1 | 0 / 36 (0.00%) 0 |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Increased viscosity of bronchial secretion subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Psychiatric disorders | | | |
| Insomnia subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Investigations | | | |
| Alanine aminotransferase increased subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Aspartate aminotransferase increased subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Blood bilirubin increased subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Blood creatine phosphokinase increased | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 36 (2.78%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood glucose increased | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Electrocardiogram T wave inversion | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Glomerular filtration rate decreased | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lipids abnormal | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pregnancy test positive | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Limb injury | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth fracture | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Burning sensation | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eye disorders | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| Swelling of eyelid subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Ulcerative keratitis subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Dyspepsia subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Nausea subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 1 / 36 (2.78%) 1 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis atopic subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 3 / 36 (8.33%) 3 | 1 / 36 (2.78%) 1 |
| Pruritus subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Acne subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Dermatitis contact subjects affected / exposed occurrences (all) | 1 / 37 (2.70%) 1 | 1 / 36 (2.78%) 1 | 1 / 36 (2.78%) 1 |
| Dry skin subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Eczema subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 1 / 36 (2.78%) 1 | 0 / 36 (0.00%) 0 |
| Erythema subjects affected / exposed occurrences (all) | 0 / 37 (0.00%) 0 | 0 / 36 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Granuloma annulare | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photosensitivity reaction | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin discolouration | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin irritation | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 36 (2.78%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Solar urticaria | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Renal and urinary disorders | | | |
| Dysuria | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Back pain | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 36 (2.78%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infections and infestations | | | |
| Influenza | | | |
| subjects affected / exposed | 2 / 37 (5.41%) | 0 / 36 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 2 | 0 | 1 |
| Nasopharyngitis | | | |

| | | | |
|-----------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 3 / 37 (8.11%) | 2 / 36 (5.56%) | 4 / 36 (11.11%) |
| occurrences (all) | 3 | 3 | 4 |
| Urinary tract infection | | | |
| subjects affected / exposed | 2 / 37 (5.41%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Bacterial allergy | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 36 (2.78%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eczema infected | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 36 (2.78%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Furuncle | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 1 / 36 (2.78%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes simplex | | | |

| | | | |
|-----------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Kaposi's varicelliform eruption | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 1 / 36 (2.78%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Staphylococcal skin infection | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vaginal infection | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral pharyngitis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral rhinitis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 36 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 1 / 36 (2.78%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |

| Non-serious adverse events | PF-06700841 0.3% Cream BID | PF-06700841 1.0% Cream BID | |
|---|-------------------------------|-------------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 9 / 36 (25.00%) | 14 / 37 (37.84%) | |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Pregnancy | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| General disorders and administration site conditions | | | |
| Application site erythema | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 1 / 37 (2.70%) | |
| occurrences (all) | 0 | 1 | |
| Application site pruritus | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Administration site warmth | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Application site acne | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 1 / 37 (2.70%) | |
| occurrences (all) | 0 | 1 | |
| Application site pain | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 1 / 37 (2.70%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|--|----------------|----------------|--|
| Chills | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pain | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vessel puncture site haematoma | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Immune system disorders | | | |
| Allergy to arthropod sting | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Cockroach allergy | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Mite allergy | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Allergy to animal | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Reproductive system and breast disorders | | | |
| Menstruation irregular | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Metrorrhagia | | | |

| | | | |
|--|---------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 37 (0.00%) 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 1 / 36 (2.78%) | 0 / 37 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Increased viscosity of bronchial secretion | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Psychiatric disorders | | | |
| Insomnia | | | |
| subjects affected / exposed | 1 / 36 (2.78%) | 0 / 37 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 1 / 37 (2.70%) | |
| occurrences (all) | 0 | 1 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 1 / 37 (2.70%) | |
| occurrences (all) | 0 | 1 | |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Blood glucose increased | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Electrocardiogram T wave inversion | | | |

| | | | |
|--|----------------|----------------|--|
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Glomerular filtration rate decreased | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Lipids abnormal | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pregnancy test positive | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Injury, poisoning and procedural complications | | | |
| Limb injury | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Tooth fracture | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 1 / 37 (2.70%) | |
| occurrences (all) | 0 | 1 | |
| Nervous system disorders | | | |
| Burning sensation | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Headache | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Eye disorders | | | |
| Swelling of eyelid | | | |
| subjects affected / exposed | 1 / 36 (2.78%) | 0 / 37 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ulcerative keratitis | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Gastrointestinal disorders | | | |

| | | | |
|--|----------------|----------------|--|
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 1 / 37 (2.70%) | |
| occurrences (all) | 0 | 1 | |
| Nausea | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 2 / 37 (5.41%) | |
| occurrences (all) | 0 | 2 | |
| Pruritus | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Acne | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 1 / 37 (2.70%) | |
| occurrences (all) | 0 | 1 | |
| Dry skin | | | |
| subjects affected / exposed | 1 / 36 (2.78%) | 0 / 37 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eczema | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Erythema | | | |
| subjects affected / exposed | 1 / 36 (2.78%) | 1 / 37 (2.70%) | |
| occurrences (all) | 1 | 1 | |
| Granuloma annulare | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 1 / 37 (2.70%) | |
| occurrences (all) | 0 | 1 | |
| Hyperhidrosis | | | |
| subjects affected / exposed | 1 / 36 (2.78%) | 0 / 37 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Photosensitivity reaction | | | |

| | | | |
|--|---------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 37 (0.00%) 0 | |
| Skin discolouration subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 37 (0.00%) 0 | |
| Skin irritation subjects affected / exposed occurrences (all) | 1 / 36 (2.78%) 1 | 0 / 37 (0.00%) 0 | |
| Solar urticaria subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 37 (0.00%) 0 | |
| Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 37 (0.00%) 0 | |
| Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 37 (0.00%) 0 | |
| Musculoskeletal pain subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 37 (0.00%) 0 | |
| Neck pain subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 37 (0.00%) 0 | |
| Infections and infestations Influenza subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 37 (0.00%) 0 | |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 2 / 36 (5.56%) 2 | 2 / 37 (5.41%) 2 | |
| Urinary tract infection subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 37 (0.00%) 0 | |
| Bacterial allergy | | | |

| | | |
|---------------------------------|----------------|----------------|
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Bronchitis | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Conjunctivitis | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Cystitis | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Eczema infected | | |
| subjects affected / exposed | 1 / 36 (2.78%) | 0 / 37 (0.00%) |
| occurrences (all) | 1 | 0 |
| Folliculitis | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 1 / 37 (2.70%) |
| occurrences (all) | 0 | 1 |
| Furuncle | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Gastroenteritis | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Gastroenteritis viral | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Gingivitis | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Herpes simplex | | |
| subjects affected / exposed | 1 / 36 (2.78%) | 0 / 37 (0.00%) |
| occurrences (all) | 1 | 0 |
| Kaposi's varicelliform eruption | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Laryngitis | | |

| | | |
|---|----------------|----------------|
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Oral herpes | | |
| subjects affected / exposed | 1 / 36 (2.78%) | 0 / 37 (0.00%) |
| occurrences (all) | 1 | 0 |
| Pharyngitis | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Rhinitis | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 1 / 37 (2.70%) |
| occurrences (all) | 0 | 1 |
| Skin infection | | |
| subjects affected / exposed | 1 / 36 (2.78%) | 0 / 37 (0.00%) |
| occurrences (all) | 1 | 0 |
| Staphylococcal skin infection | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Tonsillitis | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 1 / 37 (2.70%) |
| occurrences (all) | 0 | 1 |
| Upper respiratory tract infection | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 1 / 37 (2.70%) |
| occurrences (all) | 0 | 1 |
| Vaginal infection | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Viral infection | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 1 / 37 (2.70%) |
| occurrences (all) | 0 | 1 |
| Viral pharyngitis | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Viral rhinitis | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all) | 0 | 0 |
| Viral upper respiratory tract infection | | |

| | | | |
|-----------------------------|----------------|----------------|--|
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 37 (0.00%) | |
| occurrences (all) | 0 | 0 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported