Clinical trial results:
An Open-Label Extension Study Of The Safety And Clinical Utility Of IPX203 In Parkinson's Disease Patients With Motor Fluctuations

Summary

EudraCT number	2018-002234-21
Trial protocol	DE CZ ES GB PL IT
Global end of trial date	21 March 2022

Results information

Result version number	v1 (current)
This version publication date	01 July 2023
First version publication date	01 July 2023

Trial information

Trial identification

Sponsor protocol code	IPX203-B16-03

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03877510
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Impax Laboratories, LLC
Sponsor organisation address	400 Crossing Boulevard, Third Floor, Bridgewater, NJ, United States, 08807
Public contact	Pamela Fitzpatrick, Impax Laboratories, LLC, +1 631-633-2104, pfitzpatrick@amneal.com
Scientific contact	Pamela Fitzpatrick, Impax Laboratories, LLC, +1 631-633-2104, pfitzpatrick@amneal.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	21 March 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 March 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the long-term safety and clinical utility of IPX203 in the treatment of subjects with advanced Parkinson’s disease (PD) who have motor fluctuations.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with the International Conference on Harmonization (ICH) guidelines for Good Clinical Practice (GCP) and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 April 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 209
Country: Number of subjects enrolled	Czechia: 28
Country: Number of subjects enrolled	France: 10
Country: Number of subjects enrolled	Germany: 30
Country: Number of subjects enrolled	Italy: 27
Country: Number of subjects enrolled	Poland: 66
Country: Number of subjects enrolled	Spain: 39
Country: Number of subjects enrolled	United Kingdom: 10
Worldwide total number of subjects	419
EEA total number of subjects	200

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	152
From 65 to 84 years	264
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

Subjects took part in the study at 94 sites across the United States, Italy, Spain, France, United Kingdom, Czech Republic, Poland, and Germany.

Pre-assignment

Screening details:

The study IPX203-B16-03 was a 9-month, open-label extension of study IPX203-B16-02. Subjects who had successfully completed Study IPX203-B16-02 had opportunity to enroll in this open-label study. A total of 419 subjects enrolled from study IPX203-B16-02, 206 subjects from the previous IPX203 group and 213 subjects from the previous IR-CD-LD group.

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	IPX203

Arm description:

IPX203 carbidopa-levodopa (CD-LD) extended-release (ER) capsules, orally in 4 different dose strength (35-140 mg, 52.5-210 mg, 70-280 mg, 87.5-350 mg) as per Investigator's discretion.

Arm type	Experimental
Investigational medicinal product name	IPX203 CD-LD ER Capsules
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

IPX203 (carbidopa-levodopa) ER capsules orally in 4 different dose strength (35-140 mg, 52.5-210 mg, 70-280 mg, 87.5-350 mg) as per Investigator's discretion.

Number of subjects in period 1	IPX203
Started	419
Completed	352
Not completed	67
Consent withdrawn by subject	22
Adverse event, non-fatal	20
Death	6
Other	1
Non-compliance with study drug	2
Lost to follow-up	2
Lack of efficacy	14

Baseline characteristics

Reporting groups	
Reporting group title	IPX203
Reporting group description:	
IPX203 carbidopa-levodopa (CD-LD) extended-release (ER) capsules, orally in 4 different dose strength (35-140 mg, 52.5-210 mg, 70-280 mg, 87.5-350 mg) as per Investigator's discretion.	

Reporting group values	IPX203	Total	
Number of subjects	419	419	
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	66.9		
standard deviation	± 8.86	-	
Gender categorical Units: Subjects			
Female	140	140	
Male	279	279	
Race Units: Subjects			
Asian	6	6	
Black or African American	4	4	
White	406	406	
Unknown or not reported	3	3	
Ethnicity Units: Subjects			
Not Hispanic or Latino	369	369	
Hispanic or Latino	46	46	
Not reported	4	4	

End points

End points reporting groups

Reporting group title	IPX203

Reporting group description:

IPX203 carbidopa-levodopa (CD-LD) extended-release (ER) capsules, orally in 4 different dose strength (35-140 mg, 52.5-210 mg, 70-280 mg, 87.5-350 mg) as per Investigator's discretion.

Primary: Number of Subjects with Treatment-emergent Adverse Events (TEAEs)

End point title	Number of Subjects with Treatment-emergent Adverse Events (TEAEs)[1]

End point description:

An AE was defined as any untoward medical occurrence in a subject or clinical trial subject administered a medicinal product and which did not necessarily have to have a causal relationship with the treatment. An AE could therefore be any unfavorable and unintended sign (example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. A TEAE was defined as an adverse event with an onset that occurs after receiving study drug. The safety analysis set included all subjects who were treated with the open-label study drug in the study.

End point type	Primary

End point timeframe:

From first dose up to 1 day after last dose (Up to 9 months/Early Termination [ET])

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Planned analyses for these data was descriptive only.

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	419			
Units: subjects	221			

Statistical analyses

No statistical analyses for this end point

Secondary: Movement Disorders Society Version of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): Part I Score

End point title	Movement Disorders Society Version of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): Part I Score

End point description:

MDS-UPDRS was a multimodal scale assessing impairment and disability. Measure of the MDS-UPDRS - Part I: Non-Motor Aspects of Experiences of Daily Living (nM-EDL) has 2 components. Component IA contains a number of behaviors assessed by the investigator with all pertinent information from the subject and caregivers. Component IB is completed by the subject with or without help from the caregiver but independent of the investigator. Overall, there are 13 questions rated from 0 - normal to 4- severe. Total score ranges from 0 to 52. with higher scores reflecting greater severity. The Intent-to-treat analysis set (ITT) included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N"

are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category. ET stands for early termination.

End point type	Secondary

End point timeframe:

Baseline, Month 3, Month 6 and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	410			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=410)	9.9 (± 6.27)			
Month 3 (n=390)	10.6 (± 6.43)			
Month 6 (n=362)	10.7 (± 6.21)			
Month 9/ET (n=393)	11.0 (± 6.72)			

Statistical analyses

No statistical analyses for this end point

Secondary: Movement Disorders Society Version of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): Part IV Score

End point title	Movement Disorders Society Version of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): Part IV Score

End point description:

Part 4 of the MDS-UPDRS objectively measures the disability associated with levodopa-induced dyskinesia. Disability was assessed via video analysis by unbiased blinded central raters. Disability was evaluated for communication, drinking from a cup, and ambulation items. 6 questions rated from 0 - normal to 4 severe. Total score ranges from 0 to 24. A higher score indicated more severe symptoms. The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 3, Month 6 and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	410			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=410)	6.6 (± 2.96)			
Month 3 (n=382)	6.0 (± 3.15)			
Month 6 (n=358)	6.0 (± 3.08)			
Month 9/ET (n=393)	6.6 (± 3.34)			

Statistical analyses

No statistical analyses for this end point

Secondary: Movement Disorders Society Version of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): Part II Score

End point title	Movement Disorders Society Version of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): Part II Score

End point description:

Measure of the MDS-UPDRS - Part II: Motor Aspects of Experiences of Daily Living (M-EDL) was a self-administered questionnaire overall there are 13 questions rated from 0 - normal to 4 severe. Total score ranges from 0 to 52., with a lower score indicating better motor function for daily living and higher score indicating more severe motor symptoms. The ITT included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 3, Month 6 and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	409			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=409)	12.8 (± 7.83)			
Month 3 (n=390)	13.0 (± 7.96)			
Month 6 (n=362)	12.8 (± 7.69)			
Month 9/ET (n=393)	13.6 (± 8.11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Movement Disorders Society version of the Unified Parkinson's disease Rating Scale (MDS-UPDRS): Sums of Part II and Part III Score

End point title	Movement Disorders Society version of the Unified Parkinson's disease Rating Scale (MDS-UPDRS): Sums of Part II and Part III Score

End point description:

Sum of MDS-UPDRS Parts II and III. Part II: Motor Aspects of Experiences of Daily Living (M-EDL) self-administered questionnaire. 13 questions rated from 0 - normal to 4 severe. Total score ranges from 0 to 52. Part III: Motor Examination assesses the motor signs of PD; completed by the rater. 33 questions

rated from 0 normal to 4 severe. Total score ranges from 0 to 132. Total score ranges from 0 (no symptom) to 184 (severe symptoms), higher score indicated more severe symptoms. The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 3, Month 6, and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	409			
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline (n=409)	40.3 (± 23.09)			
Month 3 (n=379)	39.8 (± 24.15)			
Month 6 (n=356)	39.4 (± 23.24)			
Month 9/ET (n=393)	41.5 (± 22.96)			

Statistical analyses

No statistical analyses for this end point

Secondary: Movement Disorders Society Version of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): Part III Score

End point title	Movement Disorders Society Version of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): Part III Score

End point description:

Measure of the MDS-UPDRS - Part III: Motor Examination assesses the motor signs of PD; it is completed by the rater. 33 questions rated from 0 - normal to 4 severe. Total score ranges from 0 to 132, with a lower score indicating better motor function and a higher score indicating more severe motor symptoms. The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 3, Month 6, and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	410			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=410)	27.5 (± 17.23)			

Month 3 (n=379)	26.8 (± 17.90)			
Month 6 (n=357)	26.6 (± 17.50)			
Month 9/ET (n=393)	27.8 (± 16.79)			

Statistical analyses

No statistical analyses for this end point

Secondary: Movement Disorders Society Version of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Total Score

End point title	Movement Disorders Society Version of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Total Score

End point description:

Measure of MDS-UPDRS - sum total of 4 parts.Part I: Non-Motor Aspects of Experiences of Daily Living (nM-EDL) has 2 components.Component IA contains a number of behaviors assessed by investigator.Component IB is completed by subject.Overall, there are 13 questions rated from 0 normal to 4 severe.Total score ranges from 0 to 52, higher score more severe symptoms.Part II: Motor Aspects of Experiences of Daily Living (M-EDL) self-administered questionnaire.13 questions rated from 0 normal to 4 severe.Total score ranges from 0 to 52. Part III: Motor Examination assesses motor signs of PD; completed by rater. 33 questions rated from 0 normal to 4 severe.Total score ranges 0 to 132 Part IV: Motor Complications; completed by rater. 6 questions rated from 0 normal to 4 severe.Total score ranges from 0 to 24.Overall sum ranges from 0-260. ITT set was used.Here “N” are subjects who were evaluable for outcome measure; "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 3, Month 6 and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	409			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=409)	56.7 (± 28.64)			
Month 3 (n=379)	56.5 (± 30.14)			
Month 6 (n=355)	56.0 (± 28.92)			
Month 9/ET (n=393)	59.0 (± 29.11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Patient Global Impression of Severity (PGI-S) Score

End point title	Patient Global Impression of Severity (PGI-S) Score

End point description:

The PGI-S was a subject answered assessment rating Parkinson's disease severity on a scale of 1 to 7; 1 being normal not at all ill and 7 extremely severely ill. Higher value indicates increased improvement. The ITT set included all subjects who were treated with the open-label study drug in the study and have

at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 3, Month 6 and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	409			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=409)	3.7 (± 1.02)			
Month 3 (n=390)	3.8 (± 1.00)			
Month 6 (n=363)	3.7 (± 0.99)			
Month 9/ET (n=393)	3.8 (± 1.12)			

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical Global Impression of Severity (CGI-S) Score

End point title	Clinical Global Impression of Severity (CGI-S) Score

End point description:

The CGI-I was intended as a measure of change in health status. CGI-I scores ranged from 1 (very much improved) through to 7 (very much worse). For the CGI-I, subjects were divided into one of two groups, Responders or Progressors. Responders were scored on a scale of 1-4 which was rated as "no change", "minimally improved", "much improved" or "very much improved." Progressors were scored on a scale of 5-7 which was rated as "minimally worse", "much worse" or "very much worse." The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 3, Month 6 and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	409			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=409)	3.8 (± 0.87)			
Month 3 (n=383)	3.8 (± 0.92)			
Month 6 (n=358)	3.7 (± 0.87)			
Month 9/ET (n=392)	3.8 (± 0.97)			

Statistical analyses

No statistical analyses for this end point

Secondary: 39-item Parkinson’s Disease Questionnaire (PDQ-39) Total Score

End point title	39-item Parkinson’s Disease Questionnaire (PDQ-39) Total Score

End point description:

The PDQ-39 was a disease-specific instrument designed to measure aspects of health that were relevant to subjects with PD, and which may not be included in general health status questionnaires. It evaluated the 8 domains using 39-items of mobility, activities of daily living, emotional well-being, stigma, social support, cognition, communication and bodily discomfort. Total scores were calculated for the entire questionnaire and each domain. The full range of the PDQ-39 Summary Index score is from 0 (no subject-related symptoms/quality of life unaffected) to 100 (highest subject-related symptoms/low quality of life). The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed “N” are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 3, Month 6 and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	406			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=406)	41.7 (± 27.71)			
Month 3 (n=392)	42.7 (± 27.73)			
Month 6 (n=364)	42.8 (± 28.15)			
Month 9/ET (n=390)	45.1 (± 29.45)			

Statistical analyses

No statistical analyses for this end point

Secondary: Parkinson Anxiety Scale (PAS) Total Score

End point title	Parkinson Anxiety Scale (PAS) Total Score

End point description:

PAS was 12-item subject or observer rated questionnaire with 3 domains: persistent anxiety measured by 5 questions (Each question ranged from 0 not at all, or never to 4 severe, or nearly always. Best score is 0; worst score is 20., episodic anxiety measured by 4 questions (Each question ranged from 0 never to 4 nearly always. Best score is 0; worst score is 16. and avoidance anxiety measured by 3

questions (Each question ranges from 0 - never to 4 - nearly always. Best score is 0; worst score is 16). Total score is the sum of the 12 item scores, with a range of 0 to 48; a lower value is desirable. Total score was calculated for the entire questionnaire and each domain. The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment.Here “N” are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 3, Month 6 and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	408			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=408)	10.4 (± 8.18)			
Month 3 (n=390)	10.3 (± 8.20)			
Month 6 (n=365)	10.3 (± 7.67)			
Month 9/ET (n=392)	11.1 (± 8.57)			

Statistical analyses

No statistical analyses for this end point

Secondary: Non-Motor Symptom Assessment Scale (NMSS) for Parkinson's Disease (PD) Total Score

End point title	Non-Motor Symptom Assessment Scale (NMSS) for Parkinson's Disease (PD) Total Score

End point description:

The NMSS is a 9 domain (cardiovascular, sleep/fatigue, mood/cognition, perceptual problems, attention/memory, gastrointestinal, urinary, sexual function, and miscellaneous) 30 question scale rating symptom severity on a scale of 0-3 with 3 being most severe; and frequency on a scale of 1-4 with 4 being most frequent. Each question is answered with a severity and frequency rating which are then multiplied. The sum of the products gives the total score. Total scores were calculated for the entire questionnaire and each domain. Zero is the best score and 360 is the worst score. The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed “N” are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 3, Month 6 and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	407			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=407)	32.0 (± 28.95)			
Month 3 (n=388)	32.5 (± 28.49)			
Month 6 (n=362)	33.4 (± 29.19)			
Month 9/ET (n=392)	35.3 (± 30.08)			

Statistical analyses

No statistical analyses for this end point

Secondary: Parkinson’s Disease Sleep Scale-2 (PDSS-2) Total Score

End point title	Parkinson’s Disease Sleep Scale-2 (PDSS-2) Total Score

End point description:

PDSS-2 was a 15-item self-reported questionnaire. Three domains are defined: disturbed sleep, motor symptoms at night, PD symptoms at night. Total score was calculated for the entire questionnaire and each domain. The PDSS-2 domain scores range from 0 to 20 and the total score is a sum of the 3 domains and ranges from 0 to 60. Higher scores indicate higher frequency and more severe impact of PD on sleep. The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed “N” are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 3, Month 6 and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	410			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=410)	16.6 (± 9.72)			
Month 3 (n=389)	15.8 (± 9.16)			
Month 6 (n=363)	16.1 (± 9.29)			
Month 9/ET (n=387)	16.2 (± 9.28)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Treatment Satisfaction Assessment (TSA) Scores 5-7 (Satisfied) versus Scores 1-4 (Dissatisfied or Neutral)

End point title	Percentage of Subjects with Treatment Satisfaction Assessment (TSA) Scores 5-7 (Satisfied) versus Scores 1-4 (Dissatisfied or Neutral)

End point description:

The TSA was a subject answered assessment rating treatment satisfaction on a scale of 1 to 7; 1 being least satisfied and 7 being most satisfied. The responses were as follows: 1= Very much dissatisfied, 2 = Very dissatisfied, 3 = Somewhat dissatisfied, 4 = Neither satisfied nor dissatisfied, 5 = Somewhat satisfied, 6 = Very satisfied, 7 = Very much satisfied. The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Month 3, Month 6 and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	392			
Units: percentage of subjects				
number (not applicable)				
Month 3:5-7 (satisfied) (n=392)	80.4			
Month 3:1-4 (dissatisfied or neutral) (n=392)	19.6			
Month 6:5-7 (satisfied) (n=365)	84.4			
Month 6:1-4 (dissatisfied or neutral) (n=365)	15.6			
Month 9/ET:5-7 (satisfied) (n=392)	76.3			
Month 9/ET:1-4 (dissatisfied or neutral) (n=392)	23.7			

Statistical analyses

No statistical analyses for this end point

Secondary: TSA Score

End point title	TSA Score

End point description:

The TSA was a subject answered assessment rating treatment satisfaction on a scale of 1 to 7; 1 being least satisfied and 7 being most satisfied. The responses were as follows: 1= Very much dissatisfied, 2 = Very dissatisfied, 3 = Somewhat dissatisfied, 4 = Neither satisfied nor dissatisfied, 5 = Somewhat satisfied, 6 = Very satisfied, 7 = Very much satisfied. The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Month 3, Month 6 and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	392			
Units: score on a scale				
arithmetic mean (standard deviation)				
Month 3 (n=392)	5.2 (± 1.25)			
Month 6 (n=365)	5.4 (± 1.19)			
Month 9/ET (n=392)	5.2 (± 1.39)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in MDS-UPDRS: Part II Score

End point title	Change From Baseline in MDS-UPDRS: Part II Score

End point description:

Measure of the MDS-UPDRS - Part II: Motor Aspects of Experiences of Daily Living (M-EDL) was a self-administered questionnaire overall there are 13 questions rated from 0 - normal to 4 severe. Total score ranges from 0 to 52., with a lower score indicating better motor function for daily living and higher score indicating more severe motor symptoms. The ITT included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	409			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=409)	12.8 (± 7.83)			
Change at Month 9/ET (n=391)	0.9 (± 4.81)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in MDS-UPDRS: Part III Score

End point title	Change From Baseline in MDS-UPDRS: Part III Score

End point description:

Measure of the MDS-UPDRS - Part III: Motor Examination assesses the motor signs of PD; it is completed by the rater. 33 questions rated from 0 - normal to 4 severe. Total score ranges from 0 to 132., with a lower score indicating better motor function and a higher score indicating more severe motor symptoms. The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	410			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=410)	27.5 (± 17.23)			
Change at Month 9/ET (n=392)	0.6 (± 11.29)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in MDS-UPDRS: Total Score

End point title	Change From Baseline in MDS-UPDRS: Total Score

End point description:

Measure of MDS-UPDRS - sum total of 4 parts. Part I: Non-Motor Aspects of Experiences of Daily Living (nM-EDL) has 2 components.Component IA contains a number of behaviors assessed by the investigator. Component IB is completed by the subject. Overall, there are 13 questions rated from 0 normal to 4 severe.Total score ranges from 0 to 52. Part II: Motor Aspects of Experiences of Daily Living (M-EDL) self-administered questionnaire. 13 questions rated from 0 normal to 4 severe.Total score ranges from 0 to 52. Part III: Motor Examination assesses the motor signs of PD; completed by the rater. 33 questions rated from 0 normal to 4 severe.Total score ranges from 0 to 132 Part IV: Motor Complications; completed by the rater. 6 questions rated from 0 - normal to 4 severe. Total score ranges from 0 to 24.Overall sum ranges from 0-260. ITT set was used. Here "N" are the subjects who were evaluable for the outcome measure; "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	409			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=409)	56.7 (± 28.64)			
Change at Month 9/ET (n=391)	2.7 (± 16.44)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in MDS-UPDRS: Part I Score

End point title	Change From Baseline in MDS-UPDRS: Part I Score

End point description:

MDS-UPDRS was a multimodal scale assessing impairment and disability. Measure of the MDS-UPDRS - Part I: Non-Motor Aspects of Experiences of Daily Living (nM-EDL) has 2 components. Component IA contains a number of behaviors assessed by the investigator with all pertinent information from the subject and caregivers. Component IB is completed by the subject with or without help from the caregiver but independent of the investigator. Overall there are 13 questions rated from 0 - normal to 4-severe. Total score ranges from 0 to 52. with higher scores reflecting greater severity. The ITT included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	410			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=410)	9.9 (± 6.27)			
Change at Month 9/ET (n=392)	1.2 (± 4.56)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in MDS-UPDRS: Sums of Part II and Part III Score

End point title	Change From Baseline in MDS-UPDRS: Sums of Part II and Part III Score

End point description:

Sum of MDS-UPDRS Parts II and III. Part II: Motor Aspects of Experiences of Daily Living (M-EDL) self-administered questionnaire. 13 questions rated from 0 - normal to 4 severe. Total score ranges from 0 to 52. Part III: Motor Examination assesses the motor signs of PD; completed by the rater. 33 questions rated from 0 normal to 4 severe. Total score ranges from 0 to 132. Total score ranges from 0 to 184. The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	409			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=409)	40.3 (± 23.09)			
Change at Month 9/ET (n=391)	1.5 (± 13.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PGI-S >= 4 and PGI-S >= 5 Score

End point title	Percentage of Subjects With a PGI-S >= 4 and PGI-S >= 5 Score

End point description:

The PGI-S was a subject answered assessment rating Parkinson's disease severity on a scale of 1 to 7; 1 being normal not at all ill and 7 extremely severely ill. Higher value indicates increased improvement. The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 3, Month 6, and Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	409			
Units: percentage of subjects				
number (not applicable)				
Baseline: >=4 (n=409)	64.5			

Baseline: >=5 (n=409)	20.3			
Month 3: >=4 (n=390)	66.7			
Month 3: >=5 (n=390)	20.0			
Month 6: >=4 (n=363)	62.5			
Month 6: >=5 (n=363)	20.7			
Month 9/ET: >=4 (n=393)	65.4			
Month 9/ET: >=5 (n=393)	22.6			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in MDS-UPDRS: Part IV Score

End point title	Change From Baseline in MDS-UPDRS: Part IV Score

End point description:

Part 4 of the MDS-UPDRS objectively measures the disability associated with levodopa-induced dyskinesia. Disability was assessed via video analysis by unbiased blinded central raters. Disability was evaluated for communication, drinking from a cup, and ambulation items. 6 questions rated from 0 - normal to 4 severe. Total score ranges from 0 to 24. A higher score indicated more severe symptoms. The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	410			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=410)	6.6 (± 2.96)			
Change at Month 9/ET (n=392)	0.0 (± 2.64)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PGI-S Score

End point title	Change From Baseline in PGI-S Score

End point description:

The PGI-S was a subject answered assessment rating Parkinson's disease severity on a scale of 1 to 7; 1 being normal not at all ill and 7 extremely severely ill. Higher value indicates increased improvement. The ITT set included all subjects who were treated with the open-label study drug in the study and have

at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	409			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=409)	3.7 (± 1.02)			
Change at Month 9/ET (n=391)	0.0 (± 1.07)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a CGI-S >= 4 and CGI-S >= 5 Score

End point title	Percentage of Subjects With a CGI-S >= 4 and CGI-S >= 5 Score

End point description:

The CGI-I was intended as a measure of change in health status. CGI-I scores ranged from 1 (very much improved) through to 7 (very much worse). For the CGI-I, subjects were divided into one of two groups, Responders or Progressors. Responders were scored on a scale of 1-4 which was rated as "no change", "minimally improved", "much improved" or "very much improved." Progressors were scored on a scale of 5-7 which was rated as "minimally worse", "much worse" or "very much worse." The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline and Month 9/ET

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	409			
Units: percentage of subjects				
number (not applicable)				
Baseline: >=4 (n=409)	66.7			
Baseline: >=5 (n=409)	19.6			
Month 3: >=4 (n=383)	64.8			
Month 3: >=5 (n=383)	18.3			

Month 6: >=4 (n=358)	61.2			
Month 6: >=5 (n=358)	14.0			
Month 9/ET: >=4 (n=392)	65.3			
Month 9/ET: >=5 (n=392)	17.6			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in CGI-S Score

End point title	Change From Baseline in CGI-S Score

End point description:

The CGI-I was intended as a measure of change in health status. CGI-I scores ranged from 1 (very much improved) through to 7 (very much worse). For the CGI-I, subjects were divided into one of two groups, Responders or Progressors. Responders were scored on a scale of 1-4 which was rated as "no change", "minimally improved", "much improved" or "very much improved." Progressors were scored on a scale of 5-7 which was rated as "minimally worse", "much worse" or "very much worse." The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category. Negative score= not ill.

End point type	Secondary

End point timeframe:

Baseline, Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	409			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=409)	3.8 (± 0.87)			
Change at Month 9/ET (n=390)	0.0 (± 0.81)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in NMSS for Parkinson's Disease (PD) Total Score

End point title	Change From Baseline in NMSS for Parkinson's Disease (PD) Total Score

End point description:

The NMSS is a 9 domain (cardiovascular, sleep/fatigue, mood/cognition, perceptual problems, attention/memory, gastrointestinal, urinary, sexual function, and miscellaneous) 30 question scale rating symptom severity on a scale of 0-3 with 3 being most severe; and frequency on a scale of 1-4 with 4 being most frequent. Each question is answered with a severity and frequency rating which are then multiplied. The sum of the products gives the total score. Total scores were calculated for the entire questionnaire and each domain. Zero is the best score and 360 is the worst score. The ITT set

included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	407			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=407)	32.0 (± 28.95)			
Change at Month 9/ET (n=389)	3.8 (± 22.33)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PAS: Total Score

End point title	Change From Baseline in PAS: Total Score

End point description:

PAS was 12-item subject or observer rated questionnaire with 3 domains: persistent anxiety measured by 5 questions (Each question ranged from 0 not at all, or never to 4 severe, or nearly always. Best score is 0; worst score is 20., episodic anxiety measured by 4 questions (Each question ranged from 0 never to 4 nearly always. Best score is 0; worst score is 16. and avoidance anxiety measured by 3 questions (Each question ranges from 0 - never to 4 - nearly always. Best score is 0; worst score is 16). Total score is the sum of the 12 item scores, with a range of 0 to 48; a lower value is desirable. Total score was calculated for the entire questionnaire and each domain. The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are subjects who were evaluable for outcome measure; "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	408			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=408)	10.4 (± 8.18)			
Change at Month 9/ET (n=389)	0.9 (± 6.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PDSS-2: Total Score

End point title	Change From Baseline in PDSS-2: Total Score

End point description:

PDSS-2 was a 15-item self-reported questionnaire. Three domains are defined: disturbed sleep, motor symptoms at night, PD symptoms at night. Total score was calculated for the entire questionnaire and each domain. The PDSS-2 domain scores range from 0 to 20 and the total score is a sum of the 3 domains and ranges from 0 to 60. Higher scores indicate higher frequency and more severe impact of PD on sleep. The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	410			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=410) Change at Month 9/ET (n=386)	16.6 (± 9.72) -0.1 (± 8.92)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PDQ-39 Total Score

End point title	Change From Baseline in PDQ-39 Total Score

End point description:

The PDQ-39 was a disease-specific instrument designed to measure aspects of health that were relevant to subjects with PD, and which may not be included in general health status questionnaires. It evaluated the 8 domains using 39-items of mobility, activities of daily living, emotional well-being, stigma, social support, cognition, communication and bodily discomfort. Total scores was calculated for the entire questionnaire and each domain. The full range of the PDQ-39 Summary Index score is from 0 (no subject-related symptoms/quality of life unaffected) to 100 (highest subject-related symptoms/low quality of life). The ITT set included all subjects who were treated with the open-label study drug in the study and have at least one post-baseline clinical utility assessment. Here overall number analyzed "N" are the subjects who were evaluable for the outcome measure and "n" signifies subjects who were

evaluable for each specified category.

End point type	Secondary

End point timeframe:

Baseline, Month 9

End point values	IPX203			
Subject group type	Reporting group			
Number of subjects analysed	406			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=406)	41.7 (± 27.71)			
Change at Month 9/ET (n=385)	4.4 (± 18.65)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From first dose up to 1 day after last dose (Up to 9 months/Early Termination [ET])	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups	
Reporting group title	IPX203
Reporting group description:	
IPX203 CD-LD ER capsules, orally in 4 different dose strength (140 mg, 210 mg, 280 mg and 350 mg) as per Investigator's discretion.	

Serious adverse events	IPX203		
Total subjects affected by serious adverse events			
subjects affected / exposed	42 / 419 (10.02%)		
number of deaths (all causes)	6		
number of deaths resulting from adverse events	6		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lung neoplasm malignant			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Drowning			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		
Asthenia			

subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Hypersensitivity				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Pulmonary embolism				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Aspiration				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Hypoxia				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Psychiatric disorders			
Confusional state			
subjects affected / exposed	3 / 419 (0.72%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Psychotic disorder			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Hypersexuality			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Delirium			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Depression			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mental status changes			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Spinal cord injury cervical				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Overdose				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Head injury				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Joint dislocation				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Cardiogenic shock				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Atrial fibrillation				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Acute myocardial infarction				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				

subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cauda equina syndrome			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Polyneuropathy			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Parkinson's disease			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Freezing phenomenon			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syncope			

subjects affected / exposed	2 / 419 (0.48%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	3 / 419 (0.72%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal distension			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		

Volvulus			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Renal and urinary disorders			
Neurogenic bladder			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Lumbar spinal stenosis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Scoliosis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Herpes zoster			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Encephalitis			

subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural infection				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pneumonia				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal infection				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
COVID-19				
subjects affected / exposed	3 / 419 (0.72%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypokalemia				

subjects affected / exposed	1 / 419 (0.24%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	IPX203		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	221 / 419 (52.74%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lung neoplasm malignant			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Bladder neoplasm			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Vascular disorders			
Hypotension			
subjects affected / exposed	3 / 419 (0.72%)		
occurrences (all)	3		
Hypertensive crisis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Peripheral venous disease			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Haematoma			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Orthostatic hypotension			
subjects affected / exposed	6 / 419 (1.43%)		
occurrences (all)	6		
Hypertension			
subjects affected / exposed	6 / 419 (1.43%)		
occurrences (all)	6		
Deep vein thrombosis			

subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Surgical and medical procedures			
Knee arthroplasty			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Abscess drainage			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Tooth extraction			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Chest discomfort			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Chills			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Drowning			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Drug ineffective			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Malaise			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Chest pain			

subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Oedema peripheral			
subjects affected / exposed	5 / 419 (1.19%)		
occurrences (all)	5		
Pyrexia			
subjects affected / exposed	4 / 419 (0.95%)		
occurrences (all)	4		
Pain			
subjects affected / exposed	3 / 419 (0.72%)		
occurrences (all)	3		
Non-cardiac chest pain			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Prostatitis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Vaginal odour			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Sleep apnoea syndrome			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Pulmonary embolism			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Chronic obstructive pulmonary disease			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		

Cough subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1			
Rhinitis allergic subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1			
Rhinorrhoea subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1			
Dysphonia subjects affected / exposed occurrences (all)	2 / 419 (0.48%) 2			
Aspiration subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1			
Wheezing subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1			
Pleural effusion subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1			
Bronchospasm subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1			
Asthma subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1			
Dyspnoea subjects affected / exposed occurrences (all)	2 / 419 (0.48%) 2			
Hypoxia subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1			
Lower respiratory tract congestion subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1			

Psychiatric disorders			
Delusion			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Compulsions			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Anxiety			
subjects affected / exposed	4 / 419 (0.95%)		
occurrences (all)	4		
Affect lability			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Acute psychosis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Abnormal dreams			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Psychotic disorder			
subjects affected / exposed	3 / 419 (0.72%)		
occurrences (all)	3		
Panic attack			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Depressed mood			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Delirium			
subjects affected / exposed	3 / 419 (0.72%)		
occurrences (all)	3		
Rapid eye movement sleep behaviour disorder			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Rapid eye movements sleep abnormal			

subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Hallucination, visual				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences (all)	2			
Hallucination				
subjects affected / exposed	8 / 419 (1.91%)			
occurrences (all)	8			
Depressive symptom				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Depression				
subjects affected / exposed	7 / 419 (1.67%)			
occurrences (all)	7			
Sleep disorder				
subjects affected / exposed	3 / 419 (0.72%)			
occurrences (all)	3			
Hypersexuality				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences (all)	2			
Confusional state				
subjects affected / exposed	5 / 419 (1.19%)			
occurrences (all)	5			
Obsessive-compulsive personality disorder				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Obsessive-compulsive disorder				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Mental status changes				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Loss of libido				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			

Insomnia			
subjects affected / exposed	6 / 419 (1.43%)		
occurrences (all)	6		
Inappropriate affect			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Suicidal ideation			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Restlessness			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 419 (0.72%)		
occurrences (all)	3		
Blood creatinine increased			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Blood bilirubin increased			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Biopsy skin			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Electrocardiogram abnormal			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Blood glucose increased			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Blood potassium increased			

subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Blood urea increased				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Cardiac murmur				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences (all)	2			
Electrocardiogram low voltage				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Electrocardiogram QRS complex prolonged				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Lymphocyte count decreased				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences (all)	2			
Respiratory rate increased				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Red blood cell count decreased				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Neutrophil count increased				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences (all)	2			
Urine uric acid increased				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Weight decreased				
subjects affected / exposed	5 / 419 (1.19%)			
occurrences (all)	5			
White blood cell count increased				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			

Respiratory rate decreased			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Foot fracture			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Head injury			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Femur fracture			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Contusion			
subjects affected / exposed	4 / 419 (0.95%)		
occurrences (all)	2		
Fall			
subjects affected / exposed	21 / 419 (5.01%)		
occurrences (all)	21		
Overdose			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Injury			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Joint dislocation			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Ligament rupture			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Muscle strain			

subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Post procedural hypotension			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Skin abrasion			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Skin laceration			
subjects affected / exposed	3 / 419 (0.72%)		
occurrences (all)	3		
Spinal column injury			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Facial bones fracture			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Upper limb fracture			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Spinal cord injury cervical			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Procedural pain			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Cardiac disorders			
Aortic valve incompetence			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Tachycardia			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Acute myocardial infarction			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		

Atrioventricular block first degree			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Cardiac failure			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Cardiogenic shock			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Cardiovascular disorder			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Tachyarrhythmia			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Atrial fibrillation			
subjects affected / exposed	5 / 419 (1.19%)		
occurrences (all)	5		
Bundle branch block left			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Nervous system disorders			
Tongue biting			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Bradykinesia			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Carpal tunnel syndrome			
subjects affected / exposed	4 / 419 (0.95%)		
occurrences (all)	4		
Drop attacks			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Cauda equina syndrome			

subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Cerebrovascular accident				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Cognitive disorder				
subjects affected / exposed	3 / 419 (0.72%)			
occurrences (all)	3			
Dizziness				
subjects affected / exposed	6 / 419 (1.43%)			
occurrences (all)	6			
Memory impairment				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Hypokinesia				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Hypoaesthesia				
subjects affected / exposed	3 / 419 (0.72%)			
occurrences (all)	3			
Hyperkinesia				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Tremor				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences (all)	2			
Orthostatic hypertension				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Taste disorder				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Parkinsonism				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Paraesthesia				

subjects affected / exposed	4 / 419 (0.95%)			
occurrences (all)	4			
Syncope				
subjects affected / exposed	7 / 419 (1.67%)			
occurrences (all)	7			
Dystonia				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences (all)	2			
Sciatica				
subjects affected / exposed	5 / 419 (1.19%)			
occurrences (all)	5			
Seizure				
subjects affected / exposed	3 / 419 (0.72%)			
occurrences (all)	3			
Somnolence				
subjects affected / exposed	3 / 419 (0.72%)			
occurrences (all)	3			
Subarachnoid haemorrhage				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Headache				
subjects affected / exposed	4 / 419 (0.95%)			
occurrences (all)	4			
Motor neurone disease				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences (all)	2			
Nerve compression				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Dysaesthesia				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences (all)	2			
Brachial plexopathy				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Freezing phenomenon				

subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Epilepsy			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Parkinson's disease			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Peripheral sensorimotor neuropathy			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Polyneuropathy			
subjects affected / exposed	3 / 419 (0.72%)		
occurrences (all)	3		
Restless legs syndrome			
subjects affected / exposed	5 / 419 (1.19%)		
occurrences (all)	5		
On and off phenomenon			
subjects affected / exposed	6 / 419 (1.43%)		
occurrences (all)	6		
Neuropathy peripheral			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Dyskinesia			
subjects affected / exposed	21 / 419 (5.01%)		
occurrences (all)	21		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 419 (1.19%)		
occurrences (all)	5		
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		

Microcytic anaemia subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1		
Lymphadenopathy subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1		
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	4 / 419 (0.95%) 4		
Ear disorder subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1		
Eye disorders Uveitis subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1		
Intraocular haematoma subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1		
Cataract subjects affected / exposed occurrences (all)	4 / 419 (0.95%) 4		
Gastrointestinal disorders Dyspepsia subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1		
Dry mouth subjects affected / exposed occurrences (all)	2 / 419 (0.48%) 2		
Volvulus subjects affected / exposed occurrences (all)	2 / 419 (0.48%) 2		
Colitis subjects affected / exposed occurrences (all)	2 / 419 (0.48%) 2		
Constipation			

subjects affected / exposed	11 / 419 (2.63%)			
occurrences (all)	11			
Dental caries				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Diarrhoea				
subjects affected / exposed	3 / 419 (0.72%)			
occurrences (all)	3			
Abdominal pain upper				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences (all)	2			
Dysphagia				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Gastrooesophageal reflux disease				
subjects affected / exposed	4 / 419 (0.95%)			
occurrences (all)	4			
Hiatus hernia				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Hyperchlorhydria				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Periodontal disease				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Aptyalism				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Abdominal distension				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences (all)	2			
Abdominal discomfort				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Nausea				

subjects affected / exposed	8 / 419 (1.91%)		
occurrences (all)	8		
Vomiting			
subjects affected / exposed	6 / 419 (1.43%)		
occurrences (all)	6		
Food poisoning			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Hepatobiliary disorders			
Hepatic cyst			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	5 / 419 (1.19%)		
occurrences (all)	5		
Dermatitis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Pain of skin			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Renal and urinary disorders			
Incontinence			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Haematuria			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Neurogenic bladder			

subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Nephrolithiasis				
subjects affected / exposed	5 / 419 (1.19%)			
occurrences (all)	5			
Micturition urgency				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Ketonuria				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Hypertonic bladder				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Pollakiuria				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Renal cyst				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Urinary incontinence				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Urinary retention				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Ureterolithiasis				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Dysuria				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Chronic kidney disease				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences (all)	2			
Bladder dysfunction				

subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Acute kidney injury			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Urinary tract inflammation			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain			
subjects affected / exposed	5 / 419 (1.19%)		
occurrences (all)	5		
Muscle spasms			
subjects affected / exposed	4 / 419 (0.95%)		
occurrences (all)	4		
Flank pain			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Bursitis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Bursa disorder			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	15 / 419 (3.58%)		
occurrences (all)	15		
Arthritis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Arthralgia			

subjects affected / exposed	4 / 419 (0.95%)		
occurrences (all)	4		
Muscular weakness			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Myopathy			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Scoliosis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Plantar fasciitis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	3 / 419 (0.72%)		
occurrences (all)	3		
Osteoarthritis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Lumbar spinal stenosis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Neck pain			
subjects affected / exposed	3 / 419 (0.72%)		
occurrences (all)	3		
Tendonitis			
subjects affected / exposed	2 / 419 (0.48%)		
occurrences (all)	2		
Infections and infestations			
Gastritis viral			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		
Bronchitis			
subjects affected / exposed	1 / 419 (0.24%)		
occurrences (all)	1		

Herpes zoster				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Candida infection				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Cellulitis				
subjects affected / exposed	2 / 419 (0.48%)			
occurrences (all)	2			
COVID-19				
subjects affected / exposed	10 / 419 (2.39%)			
occurrences (all)	10			
COVID-19 pneumonia				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Abscess limb				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Gastroenteritis				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Eye infection bacterial				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Eyelid infection				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Folliculitis				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Cystitis				
subjects affected / exposed	3 / 419 (0.72%)			
occurrences (all)	3			
Gastroenteritis viral				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			

Gastrointestinal infection				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Nasopharyngitis				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Tooth infection				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Pneumonia				
subjects affected / exposed	3 / 419 (0.72%)			
occurrences (all)	3			
Post procedural infection				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Rhinitis				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Sepsis				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Tooth abscess				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Otitis media				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Urinary tract infection				
subjects affected / exposed	21 / 419 (5.01%)			
occurrences (all)	21			
Ear infection viral				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			
Lower respiratory tract infection				
subjects affected / exposed	1 / 419 (0.24%)			
occurrences (all)	1			

Encephalitis subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1		
Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences (all)	2 / 419 (0.48%) 2		
Fluid retention subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1		
Gout subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1		
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1		
Hypokalaemia subjects affected / exposed occurrences (all)	2 / 419 (0.48%) 2		
Hyperuricaemia subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1		
Decreased appetite subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1		
Vitamin D deficiency subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1		
Overweight subjects affected / exposed occurrences (all)	1 / 419 (0.24%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 June 2018	Protocol Amendment 1: Clarified the following text with regard to EMSQ (Appendix N): If you experienced any symptom in the question (Q.1) above on at least one day over the past week, indicate for this symptom (or for these symptoms) the severity to which this symptom impaired your morning activities and social interactions using the severity definitions below. Which of the early morning symptoms (if any) that you identified above and assessed severity in Q.2 above improved after taking a first morning dose of your Parkinson's medication(s)? For each symptom indicate "YES" improved, or "NO" did not improve. If you did not experience the symptom (i.e., answered 0 to Q.1 above), indicate "Did not experience".
26 November 2018	Protocol Amendment 2: Updated measures and/or instruments used in the study to the most current versions available for licensing; Clarified text in Sections 4, 7, 8.1 and Table 2; Updated storage information for consistency; Removed the C-SSRS Baseline/Screening Version. Only the C-SSRS Since Last Visit Version was required for this open-label extension study since subjects were continuing from Study IPX203-B16-02.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported