



Clinical trial results:

A Phase 1, Open-Label Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of Oral Ibrexafungerp (SCY-078) in Adolescent Female Subjects

Summary

EudraCT number	2024-000382-25
Trial protocol	Outside EU/EEA
Global end of trial date	16 December 2020

Results information

Result version number	v1 (current)
This version publication date	22 November 2024
First version publication date	22 November 2024

Trial information

Trial identification

Sponsor protocol code	SCY-078-120
-----------------------	-------------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	SCYNEXIS, Inc.
Sponsor organisation address	1 Evertrust Plaza, 13th Floor, Jersey City, United States, 07302
Public contact	Regulatory Affairs, SCYNEXIS, Inc., info@scynexis.com
Scientific contact	Regulatory Affairs, SCYNEXIS, Inc., info@scynexis.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-002535-PIP03-19
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	23 March 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	16 December 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the plasma pharmacokinetics (PK) of ibrexafungerp in adolescent female subjects between 12 and 17 years old, after receiving one day of oral BID doses of ibrexafungerp.

Protection of trial subjects:

The study was conducted in full compliance with the principles of the "Declaration of Helsinki" (as amended in Tokyo, Venice, Hong Kong, and South Africa), International Conference on Harmonization (ICH) guidelines, all of the applicable US Code of Federal Regulations (CFR), 21 CFR Part 50 & 312 and with applicable local requirements.

In obtaining and documenting informed consent and assent, the investigator was to comply with the applicable regulatory requirement(s) and was to adhere to Good Clinical Practices (GCP), local regulations, and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the study, the investigator was to have the Independent Ethics Committees (IECs) written approval of the written informed consent/assent form and any other information provided to subjects.

Before undertaking any study-related procedures with subjects, the purpose and nature of the study as well as possible adverse events (AEs) were explained to them in understandable terms and written informed consent/assent was obtained from each individual. When feasible and appropriate for subject's age, a vaginal swab sample may have been obtained for confirmation of *Candida* spp. infection via microscopic observation with 10% KOH. Obtaining a vaginal sample for 10% KOH analysis was not mandatory and the diagnosis of suspected *Candida* spp. vaginitis was enough for enrollment into the study if in the opinion of the investigator, the vaginitis would benefit from receipt of antifungal therapy. The vulvovaginal examination was age-appropriate and according to local practice.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 November 2020
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	Mauritius: 10
Worldwide total number of subjects	10
EEA total number of subjects	0

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)	10
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 10 subjects were enrolled and randomized (Cohort A, aged 12 to 14 years: 4 subjects, Cohort B, aged 15 to 17 years: 6 subjects) and received investigational study medication. Ten (10) subjects (Cohort A: 4 subjects, Cohort B: 6 subjects) received all planned doses of study medication and completed all study procedures.

Pre-assignment

Screening details:

Within 1 week prior to dosing, subjects underwent a screening visit that included assessment of medical history, physical examination, vital signs, clinical laboratory testing, and an electrocardiogram (ECG). Eligible subjects had symptoms of vaginitis. Of the 10 participants screened all 10 were eligible to continue to enrolment in the study.

Pre-assignment period milestones

Number of subjects started	10
Number of subjects completed	10

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort A (12 to 14 years of age)

Arm description:

Participants received one day of BID oral ibrexafungerp 300-mg (2 X 150-mg) citrate salt tablets given within 30 minutes of consuming a standard meal and 12 hours apart.

Arm type	Experimental
Investigational medicinal product name	ibrexafungerp
Investigational medicinal product code	SCY-078
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

BID dosing of 300mg ibrexafungerp tablets (as citrate salt). 2 x 150mg tablets.

Arm title	Cohort B (15 to 17 years of age)
------------------	----------------------------------

Arm description:

Participants received one day of BID oral ibrexafungerp 300-mg (2 X 150-mg) citrate salt tablets given within 30 minutes of consuming a standard meal and 12 hours apart.

Arm type	Experimental
Investigational medicinal product name	ibrexafungerp
Investigational medicinal product code	SCY-078
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

BID dosing of 300mg ibrexafungerp tablets (as citrate salt). 2 x 150mg tablets.

Number of subjects in period 1	Cohort A (12 to 14 years of age)	Cohort B (15 to 17 years of age)
Started	4	6
Completed	4	6

Baseline characteristics

Reporting groups

Reporting group title	Cohort A (12 to 14 years of age)
Reporting group description: Participants received one day of BID oral ibrexafungerp 300-mg (2 X 150-mg) citrate salt tablets given within 30 minutes of consuming a standard meal and 12 hours apart.	
Reporting group title	Cohort B (15 to 17 years of age)
Reporting group description: Participants received one day of BID oral ibrexafungerp 300-mg (2 X 150-mg) citrate salt tablets given within 30 minutes of consuming a standard meal and 12 hours apart.	

Reporting group values	Cohort A (12 to 14 years of age)	Cohort B (15 to 17 years of age)	Total
Number of subjects	4	6	10
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)	4	6	10
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical			
Only female participants were enrolled.			
Units: Subjects			
Female	4	6	10
Male	0	0	0

Subject analysis sets

Subject analysis set title	Pharmacokinetic Population
Subject analysis set type	Full analysis
Subject analysis set description: All subjects who receive ibrexafungerp and who have at least one quantifiable PK parameter.	
Subject analysis set title	Safety Population
Subject analysis set type	Safety analysis
Subject analysis set description: All subjects who enrolled in the study and received at least a partial tablet of ibrexafungerp. No treated subjects were excluded from the safety population.	
Subject analysis set title	Enrolled Population
Subject analysis set type	Full analysis
Subject analysis set description: All subjects who were eligible and signed informed consent	

Reporting group values	Pharmacokinetic Population	Safety Population	Enrolled Population
Number of subjects	10	10	10
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)	10	10	10
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical			
Only female participants were enrolled.			
Units: Subjects			
Female	10	10	10
Male	0	0	0

End points

End points reporting groups

Reporting group title	Cohort A (12 to 14 years of age)
Reporting group description: Participants received one day of BID oral ibrexafungerp 300-mg (2 X 150-mg) citrate salt tablets given within 30 minutes of consuming a standard meal and 12 hours apart.	
Reporting group title	Cohort B (15 to 17 years of age)
Reporting group description: Participants received one day of BID oral ibrexafungerp 300-mg (2 X 150-mg) citrate salt tablets given within 30 minutes of consuming a standard meal and 12 hours apart.	
Subject analysis set title	Pharmacokinetic Population
Subject analysis set type	Full analysis
Subject analysis set description: All subjects who receive ibrexafungerp and who have at least one quantifiable PK parameter.	
Subject analysis set title	Safety Population
Subject analysis set type	Safety analysis
Subject analysis set description: All subjects who enrolled in the study and received at least a partial tablet of ibrexafungerp. No treated subjects were excluded from the safety population.	
Subject analysis set title	Enrolled Population
Subject analysis set type	Full analysis
Subject analysis set description: All subjects who were eligible and signed informed consent	

Primary: Maximum plasma concentration (Cmax) of ibrexafungerp following the first dose

End point title	Maximum plasma concentration (Cmax) of ibrexafungerp following the first dose ^[1]
End point description: Maximum plasma concentration of ibrexafungerp (Cmax), calculated by means of noncompartmental analysis, was one of the pharmacokinetic parameters evaluated in the study.	
End point type	Primary
End point timeframe: Blood samples were collected predose (0 hours) and at 1, 2, 4, 8, and 12 (prior to the second dose) hours post first dose for determination of ibrexafungerp plasma concentrations.	

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: No inferential statistics were planned for this endpoint. Summary statistics for this parameter were described by n, arithmetic mean (mean), arithmetic mean SD, arithmetic CV%, geometric mean, geometric CV%, min, median, and max.

End point values	Cohort A (12 to 14 years of age)	Cohort B (15 to 17 years of age)	Pharmacokinetic Population	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	6	10	
Units: nM				
arithmetic mean (standard deviation)	493.6 (± 164)	589.6 (± 178)	551.2 (± 170)	

Statistical analyses

No statistical analyses for this end point

Primary: Maximum plasma concentration (Cmax) of ibrexafungerp following the second dose

End point title	Maximum plasma concentration (Cmax) of ibrexafungerp following the second dose ^[2]
-----------------	---

End point description:

Maximum plasma concentration of ibrexafungerp (Cmax), calculated by means of noncompartmental analysis, was one of the pharmacokinetic parameters evaluated in the study.

End point type	Primary
----------------	---------

End point timeframe:

Blood samples were collected at 13, 16, 24, 30, and 46 hours post first dose for determination of ibrexafungerp plasma concentrations.

Notes:

[2] - 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: No inferential statistics were planned for this endpoint. Summary statistics for this parameter were described by n, arithmetic mean (mean), arithmetic mean SD, arithmetic CV%, geometric mean, geometric CV%, min, median, and max.

End point values	Cohort A (12 to 14 years of age)	Cohort B (15 to 17 years of age)	Pharmacokinetic Population	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	6	10	
Units: nM				
arithmetic mean (standard deviation)	1123.4 (± 510)	924.5 (± 155)	1004.1 (± 333)	

Statistical analyses

No statistical analyses for this end point

Primary: Area under the concentration-time curve from 0 to 12 hours (AUC0-12) for ibrexafungerp

End point title	Area under the concentration-time curve from 0 to 12 hours (AUC0-12) for ibrexafungerp ^[3]
-----------------	---

End point description:

Area under the concentration-time curve (AUC0-12) was calculated by means of noncompartmental analysis. AUC determination was based on the linear trapezoidal rule, and actual PK sample times were used for the PK analyses.

End point type	Primary
----------------	---------

End point timeframe:

Blood samples were collected predose (0 hours) and at 1, 2, 4, 8, and 12 (prior to the second dose) hours post first dose for determination of ibrexafungerp plasma concentrations.

Notes:

[3] - 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: No inferential statistics were planned for this endpoint. Summary statistics for this parameter were described by n, arithmetic mean (mean), arithmetic mean SD, arithmetic CV%, geometric mean, geometric CV%, min, median, and max.

End point values	Cohort A (12 to 14 years of age)	Cohort B (15 to 17 years of age)	Pharmacokinetic Population	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	6	10	
Units: hr.nM				
arithmetic mean (standard deviation)	4357 (± 1276)	4720 (± 1333)	4574 (± 1251)	

Statistical analyses

No statistical analyses for this end point

Primary: Area under the concentration-time curve from 12 to 24 hours (AUC₁₂₋₂₄) for ibrexafungerp

End point title	Area under the concentration-time curve from 12 to 24 hours (AUC ₁₂₋₂₄) for ibrexafungerp ^[4]
-----------------	--

End point description:

Area under the concentration-time curve (AUC₁₂₋₂₄) was calculated by means of noncompartmental analysis. AUC determination was based on the linear trapezoidal rule, and actual PK sample times were used for the PK analyses.

End point type	Primary
----------------	---------

End point timeframe:

Blood samples were collected at 12 (prior to the second dose), 13, 16 and 24 hours post first dose for determination of ibrexafungerp plasma concentrations.

Notes:

[4] - 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: No inferential statistics were planned for this endpoint. Summary statistics for this parameter were described by n, arithmetic mean (mean), arithmetic mean SD, arithmetic CV%, geometric mean, geometric CV%, min, median, and max.

End point values	Cohort A (12 to 14 years of age)	Cohort B (15 to 17 years of age)	Pharmacokinetic Population	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	6	10	
Units: h.nM				
arithmetic mean (standard deviation)	9982 (± 2996)	9160 (± 1702)	9489 (± 2187)	

Statistical analyses

No statistical analyses for this end point

Primary: Area under the concentration-time curve from 12 hours to infinity (AUC_{12-∞}) for ibrexafungerp

End point title	Area under the concentration-time curve from 12 hours to infinity (AUC _{12-∞}) for ibrexafungerp ^[5]
-----------------	---

End point description:

Area under the concentration-time curve (AUC_{12-∞}) was calculated by means of noncompartmental analysis. AUC determination was based on the linear trapezoidal rule, and actual PK sample times were used for the PK analyses. The AUC from the last measurable concentration (C_{last}) to infinity (AUC_{t-∞}) was calculated as C_{last}/λ_z. If the calculated AUC_{t-∞} (extrapolated AUC, where t was 12 hours) was

greater than 20% of the calculated value of AUC0-∞, then only AUC12-24 was reported.

End point type	Primary
----------------	---------

End point timeframe:

Blood samples were collected at 12 (prior to the second dose), 13, 16, 24, 30, and 46 hours post first dose for determination of ibrexafungerp plasma concentrations.

Notes:

[5] - 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: No inferential statistics were planned for this endpoint. Summary statistics for this parameter were described by n, arithmetic mean (mean), arithmetic mean SD, arithmetic CV%, geometric mean, geometric CV%, min, median, and max.

End point values	Cohort A (12 to 14 years of age)	Cohort B (15 to 17 years of age)	Pharmacokinetic Population	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	6	10	
Units: h.nM				
arithmetic mean (standard deviation)	34532 (± 15423)	27444 (± 979)	30988 (± 10517)	

Statistical analyses

No statistical analyses for this end point

Primary: Time to maximum plasma concentration (Tmax) of ibrexafungerp after the first dose

End point title	Time to maximum plasma concentration (Tmax) of ibrexafungerp after the first dose ^[6]
-----------------	--

End point description:

Time to maximum plasma concentration (Tmax) of ibrexafungerp was calculated by means of noncompartmental analysis.

End point type	Primary
----------------	---------

End point timeframe:

Blood samples were collected predose (0 hours) and at 1, 2, 4, 8, and 12 (prior to the second dose) hours post first dose for determination of ibrexafungerp plasma concentrations.

Notes:

[6] - 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: No inferential statistics were planned for this endpoint. Summary statistics for this parameter were described by n, median, min, and max.

End point values	Cohort A (12 to 14 years of age)	Cohort B (15 to 17 years of age)	Pharmacokinetic Population	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	6	10	
Units: hours				
median (full range (min-max))	8 (4 to 8)	4 (2 to 8)	6 (2 to 8)	

Statistical analyses

No statistical analyses for this end point

Primary: Time to maximum plasma concentration (Tmax) of ibrexafungerp after the second dose

End point title	Time to maximum plasma concentration (Tmax) of ibrexafungerp after the second dose ^[7]
-----------------	---

End point description:

Time to maximum plasma concentration (Tmax) of ibrexafungerp was calculated by means of noncompartmental analysis.

End point type	Primary
----------------	---------

End point timeframe:

Blood samples were collected at 13, 16, 24, 30, and 46 hours post first dose for determination of ibrexafungerp plasma concentrations.

Notes:

[7] - 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: No inferential statistics were planned for this endpoint. Summary statistics for this parameter were described by n, median, min, and max.

End point values	Cohort A (12 to 14 years of age)	Cohort B (15 to 17 years of age)	Pharmacokinetic Population	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	6	10	
Units: hours				
median (full range (min-max))	12 (4 to 12)	4 (4 to 4)	4 (4 to 12)	

Statistical analyses

No statistical analyses for this end point

Primary: Elimination half-life (t_{1/2}) of ibrexafungerp after the second dose

End point title	Elimination half-life (t _{1/2}) of ibrexafungerp after the second dose ^[8]
-----------------	---

End point description:

Elimination half-life (t_{1/2}) of ibrexafungerp after the second dose was calculated by means of noncompartmental analysis (NCA). Elimination rate constants were based on the linear trapezoidal rule, and actual PK sample times were used for the PK analyses. The t_{1/2}, if calculated, used at least 3 time points from the logarithmic terminal phase portion of the concentration time curve. If the adjusted R-squared value (Rsquared_{adjusted}) was <0.8 for the determination of the elimination rate constant, then PK parameters depending upon Kel (λ_z) were not reported (ie, t_{1/2}, AUC_{t-∞}).

End point type	Primary
----------------	---------

End point timeframe:

Blood samples were collected predose (0 hours) and at 1, 2, 4, 8, 12 (prior to the second dose), 13, 16, 24, 30, and 46 hours post first dose for determination of ibrexafungerp plasma concentrations.

Notes:

[8] - 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: No inferential statistics were planned for this endpoint. Summary statistics for this parameter were described by n, arithmetic mean (mean), arithmetic mean SD, arithmetic CV%, geometric mean, geometric CV%, min, median, and max. The t_{1/2}, harmonic mean, and pseudo SD were also presented.

End point values	Cohort A (12 to 14 years of age)	Cohort B (15 to 17 years of age)	Pharmacokinetic Population	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	6	10	
Units: hours				
arithmetic mean (standard deviation)	15.22 (± 3.41)	16.33 (± 2.62)	15.89 (± 2.83)	

Statistical analyses

No statistical analyses for this end point

Secondary: Safety and tolerability of ibrexafungerp after receiving one day of BID dosing

End point title	Safety and tolerability of ibrexafungerp after receiving one day of BID dosing
-----------------	--

End point description:

Safety and tolerability was measured by adverse events, vital signs (blood pressure, heart rate, respiratory rate, and temperature), physical examination, 12-lead electrocardiogram (ECG), and laboratory safety (biochemistry, hematology, coagulation, and urinalysis).

Adverse events were collected from the time of ascent and informed consent through 30 days after the last dose of study medication, a phone call was made to find out if there had been any AEs after the TOC/poststudy visit.

Vital signs were measured at screening, on Day 1 at predose, at 2, 4, 13, 16, 24 and 30 hours post AM dose, and the poststudy visit.

Physical exams were performed at screening and then at predose (if screening was more than 24 hours predose Day 1), 24 hours post AM dose Day 1, and the poststudy visit

A 12-lead ECG was conducted at screening, 30 hours post first dose and at the poststudy visit.

Laboratory safety tests were conducted at screening, 46 hours post first dose and at the poststudy visit.

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

End point timeframe:

Adverse events and measurements were taken throughout the study duration.

End point values	Cohort A (12 to 14 years of age)	Cohort B (15 to 17 years of age)	Safety Population	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	6	10	
Units: Number of treatment-emergent AEs	0	3	3	

Attachments (see zip file)	Tabulated Summary of Safety Parameters.pdf
----------------------------	--

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Efficacy of ibrexafungerp in the treatment of suspected candida spp. vaginitis in adolescent girls

End point title	Efficacy of ibrexafungerp in the treatment of suspected candida spp. vaginitis in adolescent girls
End point description:	
The Test of Cure (TOC) exploratory endpoint of the study was to assess the efficacy of ibrexafungerp in the treatment of suspected Candida spp. vaginitis in adolescent females with symptoms and signs of vaginitis consistent with vulvovaginal candidiasis as reported by the resolution of baseline symptoms at the Day 10 (TOC) visit. The composite score of the vulvovaginal signs and symptoms was calculated by adding the signs and symptoms scores for each subject and had a total possible score of 0 to 18. The efficacy analysis was performed for the VSS scores collected at screening, predose, and at the TOC visit. Clinical cure was defined as a composite VSS score of zero at the TOC visit.	
End point type	Other pre-specified
End point timeframe:	
Poststudy visit (Day 10 ± 3)	

End point values	Enrolled Population			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: Mean composite VVS score	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events (AEs) were collected from the time of assent and informed consent through 30 days after the last dose of study medication, a phone call was made to find out if there had been any AEs after the TOC/poststudy visit.

Adverse event reporting additional description:

Summary tables of treatment-emergent AEs (TEAE) are presented. A TEAE is defined as any AE with an onset date and time after the first dose of study drug or any event already present that worsens in severity after exposure to the treatment. A subject with more than one TEAE within a SOC (or PT) was counted only once for that SOC (or PT)

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	Cohort A (12 to 14 years of age)
-----------------------	----------------------------------

Reporting group description:

Participants received one day of BID oral ibrexafungerp 300-mg (2 X 150-mg) citrate salt tablets given within 30 minutes of consuming a standard meal and 12 hours apart.

Reporting group title	Cohort B (15 to 17 years of age)
-----------------------	----------------------------------

Reporting group description:

Participants received one day of BID oral ibrexafungerp 300-mg (2 X 150-mg) citrate salt tablets given within 30 minutes of consuming a standard meal and 12 hours apart.

Reporting group title	Enrolled Population
-----------------------	---------------------

Reporting group description: -

Serious adverse events	Cohort A (12 to 14 years of age)	Cohort B (15 to 17 years of age)	Enrolled Population
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 10 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Cohort A (12 to 14 years of age)	Cohort B (15 to 17 years of age)	Enrolled Population
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	2 / 6 (33.33%)	3 / 10 (30.00%)
Gastrointestinal disorders			
Vomiting			

subjects affected / exposed	0 / 4 (0.00%)	2 / 6 (33.33%)	2 / 10 (20.00%)
occurrences (all)	0	2	2
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	1 / 10 (10.00%)
occurrences (all)	0	1	1

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