EU Clinical Trials Register

Clinical trial results:
A Phase 1, Randomized, Open-label, Single-Dose, Crossover, Relative Bioavailability, and Food-Effect Study of a Pediatric Chewable Tablet Formulation Relative to a 375-mg Core Tablet Formulation of Telaprevir in Healthy Adult Subjects

Summary

EudraCT number	2010-021156-26
Trial protocol	Outside EU/EEA
Global end of trial date	06 August 2010

Results information

Result version number	v1 (current)
This version publication date	28 June 2016
First version publication date	07 August 2015

Trial information

Trial identification

Sponsor protocol code	VX10-950-022

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Vertex Pharmaceuticals Incorporated
Sponsor organisation address	50 Northern Avenue, Boston, MA, United States, 02210-1862
Public contact	Medical Monitor, Vertex Pharmaceuticals Incorporated, +1 617-341-6777, medicalinfo@vrtx.com
Scientific contact	Medical Monitor, Vertex Pharmaceuticals Incorporated, +1 617-341-6777, medicalinfo@vrtx.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000196-PIP01-08
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	15 October 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 August 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the bioavailability of telaprevir administered as a pediatric chewable tablet formulation relative to a 375-milligram (mg) core tablet formulation in the fed state; To evaluate the effect of food on the pharmacokinetics (PK) of telaprevir administered as a pediatric chewable tablet formulation.

Protection of trial subjects:

The study was conducted in accordance with the ethical principles stated in the Declaration of Helsinki and the International Conference on Harmonization (ICH) Guideline for Good Clinical Practice (GCP).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 June 2010
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: 18
Worldwide total number of subjects	18
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)	0
Adults (18-64 years)	18
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

At total of 18 subjects were enrolled and randomized in the study. All 18 subjects received at least 1 dose of telaprevir in either the core tablet or pediatric formulation. The numbers reported in subject disposition are in regard to study. Started = Randomized, Completed = Completed Study, Not completed = Not completed study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Dosing Sequence 1 R/TF/T

Arm description:

R = reference formulation (375 milligram (mg) core tablet formulation of telaprevir administered in the fed state), T = test formulation (250 mg pediatric chewable tablet telaprevir formulation administered in the fed state), and TF = test formulation (250 mg pediatric chewable tablet telaprevir formulation administered in the fasted state). Subject received the dose of drug in the sequence of R/TF/T in each period.

Arm type	Experimental
Investigational medicinal product name	Telaprevir
Investigational medicinal product code	VX-950
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subject receive telaprevir as 375 mg-core formulation or 250 mg pediatric chewable tablet formulation either in fasted or fed state in each period.

Arm title	Dosing Sequence 2 T/R/TF

Arm description:

Subject received the dose of drug in the sequence of T/R/TF in each period.

Arm type	Experimental
Investigational medicinal product name	Telaprevir
Investigational medicinal product code	VX-950
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subject receive telaprevir as 375 mg-core formulation or 250 mg pediatric chewable tablet formulation either in fasted or fed state in each period.

Arm title	Dosing Sequence 3 TF/T/R

Arm description:

Subject received the dose of drug in the sequence of TF/T/R in each period.

Arm type	Experimental

Investigational medicinal product name	Telaprevir
Investigational medicinal product code	VX-950
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subject receive telaprevir as 375 mg-core formulation or 250 mg pediatric chewable tablet formulation either in fasted or fed state in each period.

Arm title	Dosing Sequence 4 T/TF/R

Arm description:

Subject received the dose of drug in the sequence of T/TF/R in each period.

Arm type	Experimental
Investigational medicinal product name	Telaprevir
Investigational medicinal product code	VX-950
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subject receive telaprevir as 375 mg-core formulation or 250 mg pediatric chewable tablet formulation either in fasted or fed state in each period.

Arm title	Dosing Sequence 5 TF/R/T

Arm description:

Subject received the dose of drug in the sequence of TF/R/T in each period.

Arm type	Experimental
Investigational medicinal product name	Telaprevir
Investigational medicinal product code	VX-950
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subject receive telaprevir as 375 mg-core formulation or 250 mg pediatric chewable tablet formulation either in fasted or fed state in each period.

Arm title	Dosing Sequence 6 R/T/TF

Arm description:

Subject received the dose of drug in the sequence of R/T/TF in each period.

Arm type	Experimental
Investigational medicinal product name	Telaprevir
Investigational medicinal product code	VX-950
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subject receive telaprevir as 375 mg-core formulation or 250 mg pediatric chewable tablet formulation either in fasted or fed state in each period.

Number of subjects in period 1	Dosing Sequence 1 R/TF/T	Dosing Sequence 2 T/R/TF	Dosing Sequence 3 TF/T/R
Started	3	3	3
Completed	1	3	2
Not completed	2	0	1
Consent withdrawn by subject	-	-	-
Adverse event	1	-	-
Unspecified	1	-	-
Lost to follow-up	-	-	1

Number of subjects in period 1	Dosing Sequence 4 T/TF/R	Dosing Sequence 5 TF/R/T	Dosing Sequence 6 R/T/TF
Started	3	3	3
Completed	2	3	2
Not completed	1	0	1
Consent withdrawn by subject	1	-	-
Adverse event	-	-	-
Unspecified	-	-	-
Lost to follow-up	-	-	1

Baseline characteristics

Reporting groups

Reporting group title	Dosing Sequence 1 R/TF/T
Reporting group description:	

R = reference formulation (375 milligram (mg) core tablet formulation of telaprevir administered in the fed state), T = test formulation (250 mg pediatric chewable tablet telaprevir formulation administered in the fed state), and TF = test formulation (250 mg pediatric chewable tablet telaprevir formulation administered in the fasted state). Subject received the dose of drug in the sequence of R/TF/T in each period.

Reporting group title	Dosing Sequence 2 T/R/TF
Reporting group description:	

Subject received the dose of drug in the sequence of T/R/TF in each period.

Reporting group title	Dosing Sequence 3 TF/T/R
Reporting group description:	

Subject received the dose of drug in the sequence of TF/T/R in each period.

Reporting group title	Dosing Sequence 4 T/TF/R
Reporting group description:	

Subject received the dose of drug in the sequence of T/TF/R in each period.

Reporting group title	Dosing Sequence 5 TF/R/T
Reporting group description:	

Subject received the dose of drug in the sequence of TF/R/T in each period.

Reporting group title	Dosing Sequence 6 R/T/TF
Reporting group description:	

Subject received the dose of drug in the sequence of R/T/TF in each period.

Reporting group values	Dosing Sequence 1 R/TF/T	Dosing Sequence 2 T/R/TF	Dosing Sequence 3 TF/T/R
Number of subjects	3	3	3
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	34.3	26	46
standard deviation	± 10.69	± 3	± 8
Gender categorical			
Units: Subjects			
Female	0	0	0
Male	3	3	3

Reporting group values	Dosing Sequence 4 T/TF/R	Dosing Sequence 5 TF/R/T	Dosing Sequence 6 R/T/TF
Number of subjects	3	3	3
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	35.7	35	38.7
standard deviation	± 4.04	± 21.66	± 7.51

Gender categorical Units: Subjects			
Female	0	0	2
Male	3	3	1

Reporting group values	Total		
Number of subjects	18		
Age categorical Units: Subjects			

Age continuous
Units: years
    arithmetic mean
    standard deviation
	-		

Gender categorical Units: Subjects			
Female	2		
Male	16		

End points

End points reporting groups

Reporting group title	Dosing Sequence 1 R/TF/T

Reporting group description:

R = reference formulation (375 milligram (mg) core tablet formulation of telaprevir administered in the fed state), T = test formulation (250 mg pediatric chewable tablet telaprevir formulation administered in the fed state), and TF = test formulation (250 mg pediatric chewable tablet telaprevir formulation administered in the fasted state). Subject received the dose of drug in the sequence of R/TF/T in each period.

Reporting group title	Dosing Sequence 2 T/R/TF

Reporting group description:

Subject received the dose of drug in the sequence of T/R/TF in each period.

Reporting group title	Dosing Sequence 3 TF/T/R

Reporting group description:

Subject received the dose of drug in the sequence of TF/T/R in each period.

Reporting group title	Dosing Sequence 4 T/TF/R

Reporting group description:

Subject received the dose of drug in the sequence of T/TF/R in each period.

Reporting group title	Dosing Sequence 5 TF/R/T

Reporting group description:

Subject received the dose of drug in the sequence of TF/R/T in each period.

Reporting group title	Dosing Sequence 6 R/T/TF

Reporting group description:

Subject received the dose of drug in the sequence of R/T/TF in each period.

Subject analysis set title	Treatment R
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects who received Treatment R in any treatment period.

Subject analysis set title	Treatment T
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects who received Treatment T in any treatment period.

Subject analysis set title	Treatment TF
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects who received Treatment TF in any treatment period.

Primary: Area Under the Plasma Concentration-Time Curve From Time Zero Extrapolated to Infinity (AUC[0-infinity]) of Telaprevir

End point title	Area Under the Plasma Concentration-Time Curve From Time Zero Extrapolated to Infinity (AUC[0-infinity]) of Telaprevir

End point description:

The AUC(0-infinity) is the area under the plasma concentration-time curve from time zero extrapolated to infinite time, calculated as the sum of AUC(last) and C(last)/lambda(z); wherein AUC(last) is area under the plasma concentration-time curve from time zero to last quantifiable time, C(last) is the last observed quantifiable concentration, and lambda(z) is elimination rate constant. Analysis was performed on PK analysis set included all subjects who had received at least 1 dose of study drug.

End point type	Primary

End point timeframe:

Predose, 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 16 and 24 hours postdose on Day 1 of each period

End point values	Treatment R	Treatment T		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	17	16		
Units: nanogram*hour per milliliter (ng*hr/mL)				
arithmetic mean (standard deviation)	13191.97 (± 6689.84)	14667.41 (± 7098.81)		

Statistical analyses

Statistical analysis title	AUC[0-infinity] of Telaprevir
Comparison groups	Treatment T v Treatment R
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric Least Squares Mean ratio
Point estimate	1.12
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.956
upper limit	1.31

Primary: AUC(0-infinity) of Telaprevir – Food Effect

End point title	AUC(0-infinity) of Telaprevir – Food Effect
End point description:	

AUC(0-infinity) is defined in first primary endpoint. Analysis was performed on PK analysis set included all subjects who had received at least 1 dose of study drug.

End point type	Primary

End point timeframe:

Predose, 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 16 and 24 hours postdose on Day 1 of each period

End point values	Treatment T	Treatment TF		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	15		
Units: ng*hr/mL				
arithmetic mean (standard deviation)	14667.41 (± 7098.81)	5644.7 (± 1324.28)		

Statistical analyses

Statistical analysis title	AUC(0-infinity) of Telaprevir – Food Effect
Comparison groups	Treatment TF v Treatment T
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric Least Squares Mean ratio
Point estimate	0.356
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.301
upper limit	0.421

Primary: Area Under the Plasma Concentration-Time Curve From Time 0 to Time of the Last Observed Quantifiable Concentration (AUC[0-last]) of Telaprevir

End point title	Area Under the Plasma Concentration-Time Curve From Time 0 to Time of the Last Observed Quantifiable Concentration (AUC[0-last]) of Telaprevir

End point description:

Analysis was performed on PK analysis set included all subjects who had received at least 1 dose of study drug.

End point type	Primary

End point timeframe:

Predose, 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 16 and 24 hours postdose on Day 1 of each period

End point values	Treatment R	Treatment T		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	17	16		
Units: ng*hr/mL				
arithmetic mean (standard deviation)	12486.45 (± 6242.3)	14239.8 (± 6802.81)		

Statistical analyses

Statistical analysis title	AUC[0-last] of Telaprevir
Comparison groups	Treatment T v Treatment R

Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric Least Squares Mean ratio
Point estimate	1.15
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.993
upper limit	1.32

Primary: AUC(0-last) of Telaprevir – Food Effect

End point title	AUC(0-last) of Telaprevir – Food Effect

End point description:

Analysis was performed on PK analysis set included all subjects who had received at least 1 dose of study drug.

End point type	Primary

End point timeframe:

Predose, 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 16 and 24 hours postdose on Day 1 of each period

End point values	Treatment T	Treatment TF		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	15		
Units: ng*hr/mL				
arithmetic mean (standard deviation)	14239.8 (± 6802.81)	4903.67 (± 1814.37)		

Statistical analyses

Statistical analysis title	AUC(0-last) of Telaprevir – Food Effect
Comparison groups	Treatment TF v Treatment T
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric Least Squares Mean ratio
Point estimate	0.339
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.291
upper limit	0.396

Primary: Maximum Observed Plasma Concentration (Cmax) of Telaprevir

End point title	Maximum Observed Plasma Concentration (Cmax) of Telaprevir
End point description:	
Analysis was performed on PK analysis set included all subjects who had received at least 1 dose of study drug.	
End point type	Primary
End point timeframe:	
Predose, 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 16 and 24 hours postdose on Day 1 of each period	

End point values	Treatment R	Treatment T		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	17	16		
Units: nanogram per milliliter (ng/mL)				
arithmetic mean (standard deviation)	2295.71 (± 902.5)	2522.13 (± 1019.09)		

Statistical analyses

Statistical analysis title	(Cmax) of Telaprevir
Comparison groups	Treatment T v Treatment R
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric Least Squares Mean ratio
Point estimate	1.08
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.881
upper limit	1.33

Primary: Cmax of Telaprevir – Food Effect

End point title	Cmax of Telaprevir – Food Effect
End point description:	
Analysis was performed on PK analysis set included all subjects who had received at least 1 dose of study drug.	
End point type	Primary
End point timeframe:	
Predose, 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 16 and 24 hours postdose on Day 1 of each period	

End point values	Treatment T	Treatment TF		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	15		
Units: ng/mL				
arithmetic mean (standard deviation)	2522.13 (± 1019.09)	608.22 (± 270.98)		

Statistical analyses

Statistical analysis title	Cmax of Telaprevir – Food Effect
Comparison groups	Treatment TF v Treatment T
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric Least Squares Mean ratio
Point estimate	0.221
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.177
upper limit	0.274

Secondary: Time to Reach Cmax (tmax) of Telaprevir

End point title	Time to Reach Cmax (tmax) of Telaprevir
End point description:	
Analysis was performed on PK analysis set included all subjects who had received at least 1 dose of study drug.	
End point type	Secondary
End point timeframe:	
Predose, 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 16 and 24 hours postdose on Day 1 of each period	

End point values	Treatment R	Treatment T		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	17	16		
Units: hours				
median (full range (min-max))	5 (3.5 to 12)	5 (2.5 to 6.05)		

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax of Telaprevir – Food Effect

End point title	Tmax of Telaprevir – Food Effect
End point description:	
Analysis was performed on PK analysis set included all subjects who had received at least 1 dose of study drug.	
End point type	Secondary
End point timeframe:	
Predose, 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 16 and 24 hours postdose on Day 1 of each period	

End point values	Treatment T	Treatment TF		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	15		
Units: hours				
median (full range (min-max))	5 (2.5 to 6.05)	4 (1.5 to 6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal Elimination Half-Life (t1/2) of Telaprevir

End point title	Terminal Elimination Half-Life (t1/2) of Telaprevir
End point description:	
The t1/2 is the time measured for the plasma concentration to decrease by one-half to its original concentration. It is associated with the terminal slope of the semi logarithmic drug concentration-time curve, and is calculated as 0.693/lambda(z). Analysis was performed on PK analysis set included all subjects who had received at least 1 dose of study drug.	
End point type	Secondary
End point timeframe:	
Predose, 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 16 and 24 hours postdose on Day 1 of each period	

End point values	Treatment R	Treatment T		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	17	16		
Units: hours				
arithmetic mean (standard deviation)	3.98 (± 0.87)	3.91 (± 1.19)		

Statistical analyses

No statistical analyses for this end point

Secondary: t1/2 of Telaprevir – Food Effect

End point title	t1/2 of Telaprevir – Food Effect

End point description:

Analysis was performed on PK analysis set included all subjects who had received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Predose, 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 16 and 24 hours postdose on Day 1 of each period

End point values	Treatment T	Treatment TF		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	15		
Units: hours				
arithmetic mean (standard deviation)	3.91 (± 1.19)	4.46 (± 1.16)		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of Subjects With Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point description:

AE: any untoward medical occurrence in a subject during the study; the event does not necessarily have a causal relationship with the treatment. This includes any newly occurring event or previous condition that has increased in severity or frequency after the informed consent form is signed. SAE (subset of AE): medical event or condition, which falls into any of the following categories, regardless of its relationship to the study drug: death, life threatening adverse experience, in-patient hospitalization/prolongation of hospitalization, persistent/significant disability or incapacity, congenital anomaly/birth defect, important medical event. Analysis was performed on safety set included all subjects who had received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Up to Safety Follow-up (Day 28)

End point values	Treatment R	Treatment T	Treatment TF	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	17	16	15	
Units: subjects				
number (not applicable)				
Number of subjects with AEs	2	2	2	
Number of subjects with SAEs	0	0	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:	
Up to Safety Follow-up (Day 28)	
Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	13

Reporting groups

Reporting group title	Treatment R
Reporting group description:	
R = reference formulation (375 milligram (mg) core tablet formulation of telaprevir administered in the fed state)	
Reporting group title	Treatment T
Reporting group description:	
T = test formulation (250 mg pediatric chewable tablet telaprevir formulation administered in the fed state)	
Reporting group title	Treatment TF
Reporting group description:	
TF = test formulation (250 mg pediatric chewable tablet telaprevir formulation administered in the fasted state)	

Serious adverse events	Treatment R	Treatment T	Treatment TF
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 15 (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: 0 %

Non-serious adverse events	Treatment R	Treatment T	Treatment TF
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 17 (11.76%)	2 / 16 (12.50%)	2 / 15 (13.33%)
Investigations			
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			

HEADACHE			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
EUPHORIC MOOD			
subjects affected / exposed	0 / 17 (0.00%)	2 / 16 (12.50%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
FOLLICULITIS			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
RHINITIS			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	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