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Trial record **1 of 1** for: CICL670A2202

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Safety and Efficacy of Deferasirox (ICL670) in Patients With Iron Overload Resulting From Hereditary Hemochromatosis

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00395629

First received: November 1, 2006
Last updated: May 24, 2011
Last verified: May 2011
History of Changes

Full Text View | Tabular View | **Study Results** | Disclaimer | How to Read a Study Record

Results First Received: December 6, 2010

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Iron Overload Hereditary Hemochromatosis
Intervention:	Drug: Deferasirox (ICL670)

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Deferasirox (ICL670) 5 mg/kg/Day	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 10 mg/kg/Day	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 15 mg/kg/Day	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.

Participant Flow for 2 periods

Period 1: Core Study

	Deferasirox (ICL670) 5 mg/kg/Day	Deferasirox (ICL670) 10 mg/kg/Day	Deferasirox (ICL670) 15 mg/kg/Day
STARTED	**11**	**15**	**23**
COMPLETED	**10**	**11**	**16**
NOT COMPLETED	**1**	**4**	**7**
Adverse Event	**0**	**3**	**4**

Abnormal laboratory value(s)	0	0	1
Protocol Violation	1	0	0
Withdrawal by Subject	0	1	1
Lost to Follow-up	0	0	1

Period 2: Extension Study

	Deferasirox (ICL670) 5 mg/kg/Day	Deferasirox (ICL670) 10 mg/kg/Day	Deferasirox (ICL670) 15 mg/kg/Day
STARTED	9	6	11
COMPLETED	9	6	8
NOT COMPLETED	0	0	3
Adverse Event	0	0	2
Administrative problems	0	0	1

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Deferasirox (ICL670) 5 mg/kg/Day	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.

Deferasirox (ICL670) 10 mg/kg/Day	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 15 mg/kg/Day	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Total	Total of all reporting groups

Baseline Measures

	Deferasirox (ICL670) 5 mg/kg/Day	Deferasirox (ICL670) 10 mg/kg/Day	Deferasirox (ICL670) 15 mg/kg/Day	Total
Number of Participants [units: participants]	**11**	**15**	**23**	**49**
Age [1] [units: years] Mean (Standard Deviation)				
Core Study	**55.8 (12.78)**	**47.8 (10.26)**	**49.8 (16.41)**	**50.6 (14.04)**
Extension Study (n=9,6,11,26)	**55.7 (14.23)**	**44.8 (10.61)**	**50.1 (15.88)**	**50.8 (14.34)**
Gender, Customized [units: participants]				
Female_Core Study	**2**	**4**	**10**	**16**
Male_Core Study	**9**	**11**	**13**	**33**
Gender, Customized [units: participants]				
Female_Extension Study	**1**	**1**	**3**	**5**
Male_Extension Study	**8**	**5**	**8**	**21**
Core Participants not enrolled in the Extension	**2**	**9**	**12**	**23**

[1] The n values in the Extension Study Category are the number of participants in each Arm/Group. The last n value= 26 is the Total number

of participants.

Outcome Measures

Hide All Outcome Measures

1. Primary: Absolute Change of Serum Ferritin From Baseline to the End of Extension, by Dose Cohort (Extension Per-protocol Population) [Time Frame: 0 to 48 weeks]

Measure Type	Primary
Measure Title	Absolute Change of Serum Ferritin From Baseline to the End of Extension, by Dose Cohort (Extension Per-protocol Population)
Measure Description	Mean absolute change in serum ferritin from baseline to the end of the extension study.
Time Frame	0 to 48 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Extension Per-protocol population including all participants of the per protocol population who also were part of the extension safety population.

Reporting Groups

	Description
Deferasirox (ICL670) 5 mg/kg/Day	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 10 mg/kg/Day	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 15 mg/kg/Day	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.

Measured Values

	Deferasirox (ICL670) 5 mg/kg/Day	Deferasirox (ICL670) 10 mg/kg/Day	Deferasirox (ICL670) 15 mg/kg/Day
Number of Participants Analyzed [units: participants]	**9**	**6**	**11**
Absolute Change of Serum Ferritin From Baseline to the End of Extension, by Dose Cohort (Extension Per-protocol Population) [units: µg/L] Mean (Standard Deviation)	**-389.1 (185.35)**	**-610.5 (341.84)**	**-571.6 (552.81)**

No statistical analysis provided for Absolute Change of Serum Ferritin From Baseline to the End of Extension, by Dose Cohort (Extension Per-protocol Population)

2. Secondary: Trough Concentrations of Deferasirox (ICL670), by Dose Cohort (Per-protocol Population) [Time Frame: 4, 8, 12, 16, 20, and 24 weeks]

Measure Type	Secondary
Measure Title	Trough Concentrations of Deferasirox (ICL670), by Dose Cohort (Per-protocol Population)
Measure Description	A blood sample was collected just prior to administration of the next dose of Deferasirox (pre-dose trough level) or approximately 24 hours after the previous dose at weeks 4, 8, 12, 16, 20 and 24. The mean trough concentration at each time point was calculated.
Time Frame	4, 8, 12, 16, 20, and 24 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per-protocol population included all participants of the safety population; who received at least one dose of study drug within the core study

and had at least one safety assessment, and who did not have any major protocol deviation. n in each of the Categories is the number of participants in each arm/group who had data for that time point.

Reporting Groups

	Description
Deferasirox (ICL670) 5 mg/kg/Day	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 10 mg/kg/Day	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 15 mg/kg/Day	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.

Measured Values

	Deferasirox (ICL670) 5 mg/kg/Day	Deferasirox (ICL670) 10 mg/kg/Day	Deferasirox (ICL670) 15 mg/kg/Day
Number of Participants Analyzed [units: participants]	**11**	**15**	**22**
Trough Concentrations of Deferasirox (ICL670), by Dose Cohort (Per-protocol Population) [units: µmol/L] Mean (Standard Deviation)			
Week 4 (n=10,14,17)	**9.63 (8.783)**	**19.62 (9.502)**	**30.48 (20.201)**
Week 8 (n=10,12,17)	**8.86 (5.828)**	**23.88 (22.787)**	**27.06 (21.686)**
Week 12 (n=10,12,13)	**10.58 (11.752)**	**28.71 (23.849)**	**23.39 (11.403)**
Week 16 (n=10,11,11)	**12.38 (11.634)**	**21.62 (16.539)**	**21.80 (18.713)**
Week 20 (n=9,10,8)	**11.72 (10.316)**	**26.47 (17.934)**	**27.58 (25.324)**
Week 24 (n=10,9,6)	**14.62 (12.216)**	**21.32 (21.840)**	**26.83 (11.178)**

No statistical analysis provided for Trough Concentrations of Deferasirox (ICL670), by Dose Cohort (Per-protocol Population)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Safety Population includes all participants who received at least one dose of study drug and had at least one safety assessment.

Reporting Groups

	Description
Deferasirox (ICL670) 5 mg/kg/day_Core Study	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 10 mg/kg/day_Core Study	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 15 mg/kg/day_Core Study	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 5 mg/kg/day_Extension Study	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 10 mg/kg/day_Extension Study	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 15 mg/kg/day_Extension Study	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.

Serious Adverse Events

	Deferasirox (ICL670) 5 mg/kg/day_Core Study	Deferasirox (ICL670) 10 mg/kg/day_Core Study	Deferasirox (ICL670) 15 mg/kg/day_Core Study	Deferasirox (ICL670) 5 mg/kg/day_Extension Study	Deferasirox (ICL670) 10 mg/kg/day_Extension Study	Deferasirox (ICL670) 15 mg/kg/day_Extension Study
Total, serious adverse events						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Prostate cancer recurrent † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Safety Population includes all participants who received at least one dose of study drug and had at least one safety assessment.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Deferasirox (ICL670) 5 mg/kg/day_Core Study	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 10 mg/kg/day_Core Study	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 15 mg/kg/day_Core Study	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 5 mg/kg/day_Extension Study	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 10 mg/kg/day_Extension Study	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.
Deferasirox (ICL670) 15 mg/kg/day_Extension Study	Deferasirox (ICL670) was provided as 125 mg, 250 mg, and 500 mg tablets. Dosage was based on the participant's body weight. ICL670 was administered orally, once a day, 30 minutes prior to breakfast.

Other Adverse Events

	Deferasirox (ICL670) 5 mg/kg/day_Core Study	Deferasirox (ICL670) 10 mg/kg/day_Core Study	Deferasirox (ICL670) 15 mg/kg/day_Core Study	Deferasirox (ICL670) 5 mg/kg/day_Extension Study	Deferasirox (ICL670) 10 mg/kg/day_Extension Study	Deferasirox (ICL670 15 mg/kg/day_Extensio Study
Total, other (not including serious)						

adverse events						
# participants affected / at risk	**10/11 (90.91%)**	**14/15 (93.33%)**	**23/23 (100.00%)**	**9/9 (100.00%)**	**5/6 (83.33%)**	**11/11 (100.00%)**
Cardiac disorders						
Arrhythmia † 1						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Atrioventricular block first degree † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Congenital, familial and genetic disorders						
Hydrocele † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Ear and labyrinth disorders						
Ear pain † 1						
# participants affected / at risk	**0/11 (0.00%)**	**1/15 (6.67%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Hypoacusis † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**2/23 (8.70%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**

Mixed deafness † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**1/6 (16.67%)**	**0/11 (0.00%)**
Neurosensory hypoacusis † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Tinnitus † 1						
# participants affected / at risk	**0/11 (0.00%)**	**1/15 (6.67%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Vertigo † 1						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**2/9 (22.22%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Eye disorders						
Blindness day † 1						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Cataract † 1						
# participants affected / at risk	**0/11 (0.00%)**	**1/15 (6.67%)**	**1/23 (4.35%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Corneal opacity † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**1/6 (16.67%)**	**0/11 (0.00%)**
Eye pain † 1						

# participants affected / at risk	0/11 (0.00%)	0/15 (0.00%)	0/23 (0.00%)	0/9 (0.00%)	0/6 (0.00%)	1/11 (9.09%)
Maculopathy † [1]						
# participants affected / at risk	0/11 (0.00%)	0/15 (0.00%)	0/23 (0.00%)	1/9 (11.11%)	0/6 (0.00%)	0/11 (0.00%)
Presbyopia † [1]						
# participants affected / at risk	1/11 (9.09%)	0/15 (0.00%)	0/23 (0.00%)	0/9 (0.00%)	0/6 (0.00%)	0/11 (0.00%)
Vision blurred † [1]						
# participants affected / at risk	1/11 (9.09%)	0/15 (0.00%)	0/23 (0.00%)	1/9 (11.11%)	0/6 (0.00%)	0/11 (0.00%)
Visual acuity reduced † [1]						
# participants affected / at risk	0/11 (0.00%)	0/15 (0.00%)	0/23 (0.00%)	0/9 (0.00%)	0/6 (0.00%)	1/11 (9.09%)
Visual impairment † [1]						
# participants affected / at risk	1/11 (9.09%)	0/15 (0.00%)	0/23 (0.00%)	0/9 (0.00%)	0/6 (0.00%)	0/11 (0.00%)
Gastrointestinal disorders						
Abdominal discomfort † [1]						
# participants affected / at risk	1/11 (9.09%)	0/15 (0.00%)	1/23 (4.35%)	1/9 (11.11%)	0/6 (0.00%)	1/11 (9.09%)
Abdominal						

distension † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**2/23 (8.70%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Abdominal pain † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**3/15 (20.00%)**	**4/23 (17.39%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Abdominal pain upper † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**2/11 (18.18%)**
Constipation † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Diarrhoea † [1]						
# participants affected / at risk	**2/11 (18.18%)**	**6/15 (40.00%)**	**10/23 (43.48%)**	**2/9 (22.22%)**	**1/6 (16.67%)**	**4/11 (36.36%)**
Dyspepsia † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**2/15 (13.33%)**	**1/23 (4.35%)**	**0/9 (0.00%)**	**2/6 (33.33%)**	**1/11 (9.09%)**
Flatulence † [1]						
# participants affected / at risk	**2/11 (18.18%)**	**1/15 (6.67%)**	**2/23 (8.70%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**2/11 (18.18%)**
Frequent bowel movements † [1]						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**0/11 (0.00%)**

Gastrooesophageal reflux disease † [1]						
# participants affected / at risk	**1/11 (9.09%)**	**1/15 (6.67%)**	**1/23 (4.35%)**	**0/9 (0.00%)**	**1/6 (16.67%)**	**0/11 (0.00%)**
Gingival disorder † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Gingival pain † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Glossodynia † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Nausea † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**2/15 (13.33%)**	**6/23 (26.09%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**4/11 (36.36%)**
Retching † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Vomiting † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**3/23 (13.04%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**2/11 (18.18%)**
General disorders						

Asthenia † 1						
# participants affected / at risk	**0/11 (0.00%)**	**1/15 (6.67%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**1/6 (16.67%)**	**0/11 (0.00%)**
Chest discomfort † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Fatigue † 1						
# participants affected / at risk	**1/11 (9.09%)**	**1/15 (6.67%)**	**2/23 (8.70%)**	**2/9 (22.22%)**	**1/6 (16.67%)**	**1/11 (9.09%)**
Influenza like illness † 1						
# participants affected / at risk	**0/11 (0.00%)**	**1/15 (6.67%)**	**2/23 (8.70%)**	**0/9 (0.00%)**	**1/6 (16.67%)**	**2/11 (18.18%)**
Non-cardiac chest pain † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Oedema peripheral † 1						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Pyrexia † 1						
# participants affected / at risk	**0/11 (0.00%)**	**2/15 (13.33%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**1/6 (16.67%)**	**0/11 (0.00%)**
Hepatobiliary						

disorders						
Hepatic function abnormal † 1						
# participants affected / at risk	**0/11 (0.00%)**	**1/15 (6.67%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Immune system disorders						
Drug hypersensitivity † 1						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Seasonal allergy † 1						
# participants affected / at risk	**0/11 (0.00%)**	**1/15 (6.67%)**	**1/23 (4.35%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Infections and infestations						
Bronchitis † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**2/23 (8.70%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Gastroenteritis † 1						
# participants affected / at risk	**0/11 (0.00%)**	**1/15 (6.67%)**	**1/23 (4.35%)**	**0/9 (0.00%)**	**1/6 (16.67%)**	**0/11 (0.00%)**
Influenza † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Lower respiratory						

tract infection † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Nasopharyngitis † [1]						
# participants affected / at risk	**1/11 (9.09%)**	**1/15 (6.67%)**	**3/23 (13.04%)**	**1/9 (11.11%)**	**1/6 (16.67%)**	**1/11 (9.09%)**
Oral herpes † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**1/15 (6.67%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Pharyngitis † [1]						
# participants affected / at risk	**1/11 (9.09%)**	**1/15 (6.67%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Pneumonia † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Sinusitis † [1]						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Upper respiratory tract infection † [1]						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**1/23 (4.35%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**3/11 (27.27%)**
Urinary tract infection † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**1/15 (6.67%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**

Vulvovaginal mycotic infection † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Injury, poisoning and procedural complications						
Eye injury † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Injury † 1						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Investigations						
Alanine aminotransferase increased † 1						
# participants affected / at risk	**0/11 (0.00%)**	**3/15 (20.00%)**	**3/23 (13.04%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**2/11 (18.18%)**
Aspartate aminotransferase increased † 1						
# participants affected / at risk	**0/11 (0.00%)**	**1/15 (6.67%)**	**1/23 (4.35%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Blood alkaline phosphatase						

increased † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Blood cholesterol increased † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Blood creatine increased † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Blood creatinine increased † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**3/15 (20.00%)**	**4/23 (17.39%)**	**1/9 (11.11%)**	**2/6 (33.33%)**	**3/11 (27.27%)**
C-reactive protein increased † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Creatinine renal clearance decreased † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**1/15 (6.67%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**1/6 (16.67%)**	**0/11 (0.00%)**
Creatinine renal clearance increased † [1]						

# participants affected / at risk	0/11 (0.00%)	1/15 (6.67%)	0/23 (0.00%)	0/9 (0.00%)	1/6 (16.67%)	0/11 (0.00%)
Gamma-glutamyltransferase increased † 1						
# participants affected / at risk	0/11 (0.00%)	0/15 (0.00%)	0/23 (0.00%)	0/9 (0.00%)	0/6 (0.00%)	1/11 (9.09%)
Transaminases increased † 1						
# participants affected / at risk	0/11 (0.00%)	1/15 (6.67%)	2/23 (8.70%)	0/9 (0.00%)	0/6 (0.00%)	1/11 (9.09%)
White blood cell count increased † 1						
# participants affected / at risk	0/11 (0.00%)	0/15 (0.00%)	0/23 (0.00%)	0/9 (0.00%)	0/6 (0.00%)	1/11 (9.09%)
Musculoskeletal and connective tissue disorders						
Arthralgia † 1						
# participants affected / at risk	1/11 (9.09%)	2/15 (13.33%)	1/23 (4.35%)	1/9 (11.11%)	2/6 (33.33%)	2/11 (18.18%)
Back pain † 1						
# participants affected / at risk	1/11 (9.09%)	4/15 (26.67%)	2/23 (8.70%)	3/9 (33.33%)	2/6 (33.33%)	1/11 (9.09%)
Flank pain † 1						
# participants affected / at risk	1/11 (9.09%)	0/15 (0.00%)	0/23 (0.00%)	1/9 (11.11%)	0/6 (0.00%)	0/11 (0.00%)

Muscle spasms † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Musculoskeletal discomfort † 1						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Musculoskeletal pain † 1						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**1/23 (4.35%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**2/11 (18.18%)**
Musculoskeletal stiffness † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Myalgia † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**1/6 (16.67%)**	**0/11 (0.00%)**
Neck pain † 1						
# participants affected / at risk	**0/11 (0.00%)**	**1/15 (6.67%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Tendonitis † 1						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Neoplasms benign,						

malignant and unspecified (incl cysts and polyps)						
Prostate cancer recurrent † [1]						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Nervous system disorders						
Dizziness † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Headache † [1]						
# participants affected / at risk	**1/11 (9.09%)**	**2/15 (13.33%)**	**7/23 (30.43%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**5/11 (45.45%)**
Hypoaesthesia † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Memory impairment † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Migraine † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Neuralgia † [1]						

# participants affected / at risk	0/11 (0.00%)	1/15 (6.67%)	0/23 (0.00%)	0/9 (0.00%)	0/6 (0.00%)	0/11 (0.00%)
Syncope vasovagal † [1]						
# participants affected / at risk	0/11 (0.00%)	1/15 (6.67%)	0/23 (0.00%)	0/9 (0.00%)	0/6 (0.00%)	0/11 (0.00%)
Psychiatric disorders						
Anxiety † [1]						
# participants affected / at risk	1/11 (9.09%)	1/15 (6.67%)	0/23 (0.00%)	1/9 (11.11%)	0/6 (0.00%)	0/11 (0.00%)
Insomnia † [1]						
# participants affected / at risk	0/11 (0.00%)	0/15 (0.00%)	0/23 (0.00%)	1/9 (11.11%)	0/6 (0.00%)	0/11 (0.00%)
Renal and urinary disorders						
Calculus urinary † [1]						
# participants affected / at risk	0/11 (0.00%)	0/15 (0.00%)	0/23 (0.00%)	0/9 (0.00%)	0/6 (0.00%)	1/11 (9.09%)
Renal impairment † [1]						
# participants affected / at risk	0/11 (0.00%)	2/15 (13.33%)	1/23 (4.35%)	0/9 (0.00%)	0/6 (0.00%)	1/11 (9.09%)
Reproductive system and breast disorders						
Benign prostatic						

hyperplasia † [1]						
# participants affected / at risk	0/11 (0.00%)	0/15 (0.00%)	0/23 (0.00%)	1/9 (11.11%)	0/6 (0.00%)	0/11 (0.00%)
Erectile dysfunction † [1]						
# participants affected / at risk	0/11 (0.00%)	1/15 (6.67%)	0/23 (0.00%)	0/9 (0.00%)	0/6 (0.00%)	0/11 (0.00%)
Respiratory, thoracic and mediastinal disorders						
Cough † [1]						
# participants affected / at risk	0/11 (0.00%)	0/15 (0.00%)	0/23 (0.00%)	0/9 (0.00%)	0/6 (0.00%)	3/11 (27.27%)
Laryngeal inflammation † [1]						
# participants affected / at risk	1/11 (9.09%)	0/15 (0.00%)	0/23 (0.00%)	0/9 (0.00%)	0/6 (0.00%)	0/11 (0.00%)
Nasal congestion † [1]						
# participants affected / at risk	0/11 (0.00%)	0/15 (0.00%)	0/23 (0.00%)	0/9 (0.00%)	0/6 (0.00%)	1/11 (9.09%)
Oropharyngeal pain † [1]						
# participants affected / at risk	0/11 (0.00%)	0/15 (0.00%)	0/23 (0.00%)	0/9 (0.00%)	0/6 (0.00%)	1/11 (9.09%)
Sinus congestion † [1]						

# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Skin and subcutaneous tissue disorders						
Actinic keratosis † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Ingrowing nail † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Precancerous skin lesion † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Rash † [1]						
# participants affected / at risk	**1/11 (9.09%)**	**1/15 (6.67%)**	**4/23 (17.39%)**	**1/9 (11.11%)**	**1/6 (16.67%)**	**2/11 (18.18%)**
Rash erythematous † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Rash generalised † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**

Seborrhoeic dermatitis † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**1/15 (6.67%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**1/6 (16.67%)**	**0/11 (0.00%)**
Urticaria † [1]						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Vascular disorders						
Hot flush † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Hypertension † [1]						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**1/23 (4.35%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**1/11 (9.09%)**
Hypotension † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Orthostatic hypotension † [1]						
# participants affected / at risk	**1/11 (9.09%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**1/9 (11.11%)**	**0/6 (0.00%)**	**0/11 (0.00%)**
Peripheral coldness † [1]						
# participants affected / at risk	**0/11 (0.00%)**	**0/15 (0.00%)**	**0/23 (0.00%)**	**0/9 (0.00%)**	**0/6 (0.00%)**	**1/11 (9.09%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

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No publications provided

Responsible Party:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00395629 History of Changes
Other Study ID Numbers:	**CICL670A2202** EudraCT no. 2006-002102-57 (Registry Identifier: EudraCT)
Study First Received:	November 1, 2006
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Health Authority:	United States: Food and Drug Administration Canada: Health Canada Australia: Department of Health and Ageing Therapeutic Goods Administration Germany: Federal Institute for Drugs and Medical Devices France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Italy: Ministry of Health