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Trial record **1 of 1** for: CICL670A2203

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Expanded Access of Deferasirox to Patients With Congenital Disorders of Red Blood Cells and Chronic Iron Overload

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00235391

First received: October 6, 2005
Last updated: June 3, 2011
Last verified: June 2011
History of Changes

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

Results First Received: December 17, 2010

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Thalassemia Sickle Cell Disease Diamond Blackfan Anemia Myelofibrosis

Intervention:	Drug: Deferasirox

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
2 to < 6 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
6 to < 12 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
12 to < 16 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
16 to < 50 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
50 to < 65 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
≥ 65 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.

Participant Flow: Overall Study

	2 to < 6 Years	6 to < 12 Years	12 to < 16 Years	16 to < 50 Years	50 to < 65 Years	≥ 65 Years
STARTED	97	200	172	1164	43	7
Deferasirox Treatment	97	200	172	1164	43	7
COMPLETED	85	182	148	944	31	3
NOT COMPLETED	12	18	24	220	12	4
Adverse Event	4	5	10	72	5	2
Abnormal laboratory value(s)	3	5	4	27	1	2
Unsatisfactory therapeutic effect	0	2	2	17	0	0
Condition no longer requires treatment	3	0	0	11	1	0
Protocol deviation	0	0	1	11	0	0
Withdrawal by Subject	2	3	3	61	5	0
Lost to Follow-up	0	3	3	16	0	0
Administrative problems	0	0	0	1	0	0
Death	0	0	1	4	0	0

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
2 to < 6 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
6 to < 12 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
12 to < 16 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
16 to < 50 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
50 to < 65 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
≥ 65 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
Total	Total of all reporting groups

Baseline Measures

	2 to < 6 Years	6 to < 12 Years	12 to < 16 Years	16 to < 50 Years	50 to < 65 Years	≥ 65 Years	Total
Number of Participants [units: participants]	**97**	**200**	**172**	**1164**	**43**	**7**	**1683**
Age							

[units: years] Mean (Standard Deviation)	3.48 (1.13)	8.52 (1.64)	13.48 (1.20)	28.91 (8.06)	54.58 (3.92)	70.14 (3.98)	24.27 (12.63)
Gender [units: participants]							
Female	44	101	81	633	32	5	896
Male	53	99	91	531	11	2	787
Baseline Disease Characteristics [1] [units: participants]							
Beta-Thalassemia Major	74	118	114	905	10	0	1221
Beta-Thalassemia Intermedia	1	22	16	94	20	3	156
Sickle Cell Disease	8	41	31	93	2	1	176
Diamond-Blackfan Anemia	4	7	8	24	0	0	43
Other Diseases	10	12	3	48	11	3	87
Prior Chelation Drug Therapy [2] [units: participants]							
Deferoxamine	80	167	137	745	31	5	1165
Deferiprone	1	8	11	146	6	1	173
Deferoxamine and Deferiprone	2	16	21	269	6	0	314
Other Chelation Drug	6	6	3	4	0	0	19
Prior Chelatation Drug Information Missing	8	3	0	0	0	1	12
Reason for inadequate prior chelation therapy [3] [units: participants]							
Therapy non-compliance	57	125	106	659	25	2	974

Therapy contraindication	**1**	**7**	**6**	**29**	**1**	**1**	**45**
Therapy unacceptable toxicity	**11**	**29**	**22**	**131**	**6**	**1**	**200**
Therapy poor response	**20**	**34**	**38**	**267**	**8**	**0**	**367**
Therapy unacceptable discomfort	**2**	**2**	**0**	**78**	**3**	**2**	**87**
Reason for inadequate therapy information missing	**6**	**3**	**0**	**0**	**0**	**1**	**10**

[1] The number of participants with each disease category.
[2] The number of participants for each chelation drug category.
[3] The number of participants for each reason for inadequate prior chelation therapy category.

Outcome Measures

Hide All Outcome Measures

1. Primary: Safety Profile of Deferasirox Based Upon Drug Administration and Reporting of Serious Adverse Events [Time Frame: Baseline to end of study (Median exposure time to drug was approximately 30 weeks; Maximum exposure was 104 weeks)]

Measure Type	Primary
Measure Title	Safety Profile of Deferasirox Based Upon Drug Administration and Reporting of Serious Adverse Events
Measure Description	Safety as assessed by the number of participants with death, serious adverse events (SAE), and/or Adverse Events (AEs) leading to study drug interruption or discontinuation. Note: only treatment emergent AEs are summarized.
Time Frame	Baseline to end of study (Median exposure time to drug was approximately 30 weeks; Maximum exposure was 104 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.

The safety population, comprising all participants who received at least one dose of deferasirox during the study, was used in the analyses.

Reporting Groups

	Description
2 to < 6 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
6 to < 12 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
12 to < 16 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
16 to < 50 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
50 to < 65 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
≥ 65 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.

Measured Values

	2 to < 6 Years	6 to < 12 Years	12 to < 16 Years	16 to < 50 Years	50 to < 65 Years	≥ 65 Years
Number of Participants Analyzed [units: participants]	**97**	**200**	**172**	**1164**	**43**	**7**
Safety Profile of Deferasirox Based Upon Drug Administration and Reporting of Serious Adverse Events [units: Participants]						
Number of deaths	**0**	**0**	**1**	**4**	**0**	**0**
Non-fatal SAEs	**10**	**22**	**27**	**129**	**4**	**2**
AEs leading to discontinuation	**4**	**5**	**10**	**75**	**5**	**2**

AEs leading dose adjustment/temporary interruption	**15**	**31**	**28**	**209**	**11**	**2**

No statistical analysis provided for Safety Profile of Deferasirox Based Upon Drug Administration and Reporting of Serious Adverse Events

2. Secondary: The Change in Serum Ferritin Values From Baseline Through Completion of the Study [Time Frame: Baseline to end of study (Median exposure time to drug was approximately 30 weeks; Maximum exposure was 104 weeks)]

Measure Type	Secondary
Measure Title	The Change in Serum Ferritin Values From Baseline Through Completion of the Study
Measure Description	The number of participants with Improvement, No Change or Worsening in Serum ferritin category levels at the end of the study compared to baseline. Serum ferritin levels in µg/L were divided into to 6 categories: (<1000), (1000-<2500), (2500-<4000), (4000-<5500), (5500-<7000) and (>=7000). Improvement was defined as a shift to a lower category at the end of study compared to the category at baseline. Worsening was defined as a shift to a higher category at the end of the study compared to the category at baseline. No change was no change in category at end of study from baseline.
Time Frame	Baseline to end of study (Median exposure time to drug was approximately 30 weeks; Maximum exposure was 104 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.
Safety population defined as all participants who received at least one dose of study drug. This analysis did not include participants with unknown status at baseline and/or at the end of the study.

Reporting Groups

	Description
2 to < 6 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.

6 to < 12 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
12 to < 16 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
16 to < 50 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
50 to < 65 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.
≥ 65 Years	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.

Measured Values

	2 to < 6 Years	6 to < 12 Years	12 to < 16 Years	16 to < 50 Years	50 to < 65 Years	≥ 65 Years
Number of Participants Analyzed [units: participants]	**97**	**200**	**172**	**1164**	**43**	**7**
The Change in Serum Ferritin Values From Baseline Through Completion of the Study [units: Participants]						
Improvement	**17**	**27**	**26**	**206**	**4**	**2**
No Change	**63**	**106**	**87**	**570**	**31**	**3**
Worsening	**16**	**63**	**55**	**341**	**7**	**1**

No statistical analysis provided for The Change in Serum Ferritin Values From Baseline Through Completion of the Study

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
All Participants	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.

Serious Adverse Events

	All Participants
Total, serious adverse events	
# participants affected / at risk	**194/1683 (11.53%)**
Blood and lymphatic system disorders	
Acute chest syndrome † 1	
# participants affected / at risk	**2/1683 (0.12%)**
Anaemia † 1	
# participants affected / at risk	**2/1683 (0.12%)**
Anaemia haemolytic autoimmune † 1	
# participants affected / at risk	**2/1683 (0.12%)**
Coombs positive haemolytic anaemia † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Haemolytic anaemia † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Hypersplenism † 1	

# participants affected / at risk	3/1683 (0.18%)
Intravascular haemolysis † 1	
# participants affected / at risk	1/1683 (0.06%)
Leukopenia † 1	
# participants affected / at risk	1/1683 (0.06%)
Neutropenia † 1	
# participants affected / at risk	2/1683 (0.12%)
Pancytopenia † 1	
# participants affected / at risk	1/1683 (0.06%)
Reticulocytopenia † 1	
# participants affected / at risk	1/1683 (0.06%)
Splenomegaly † 1	
# participants affected / at risk	4/1683 (0.24%)
Cardiac disorders	
Arrhythmia † 1	
# participants affected / at risk	1/1683 (0.06%)
Atrial fibrillation † 1	
# participants affected / at risk	2/1683 (0.12%)
Cardiac failure † 1	
# participants affected / at risk	6/1683 (0.36%)
Cardiac failure acute † 1	
# participants affected / at risk	1/1683 (0.06%)
Cardiac failure congestive † 1	
# participants affected / at risk	2/1683 (0.12%)
Congestive cardiomyopathy † 1	

# participants affected / at risk	1/1683 (0.06%)
Myopericarditis † 1	
# participants affected / at risk	1/1683 (0.06%)
Pericardial effusion † 1	
# participants affected / at risk	1/1683 (0.06%)
Tachycardia † 1	
# participants affected / at risk	1/1683 (0.06%)
Ventricular dysfunction † 1	
# participants affected / at risk	1/1683 (0.06%)
Congenital, familial and genetic disorders	
Hip dysplasia † 1	
# participants affected / at risk	1/1683 (0.06%)
Sickle cell anaemia † 1	
# participants affected / at risk	2/1683 (0.12%)
Sickle cell anaemia with crisis † 1	
# participants affected / at risk	27/1683 (1.60%)
Thalassaemia † 1	
# participants affected / at risk	1/1683 (0.06%)
Thalassaemia beta † 1	
# participants affected / at risk	2/1683 (0.12%)
Ear and labyrinth disorders	
Deafness unilateral † 1	
# participants affected / at risk	1/1683 (0.06%)
Middle ear effusion † 1	
# participants affected / at risk	1/1683 (0.06%)

Eye disorders	
Retinopathy † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Gastrointestinal disorders	
Abdominal discomfort † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Abdominal pain † 1	
# participants affected / at risk	**3/1683 (0.18%)**
Abdominal pain upper † 1	
# participants affected / at risk	**2/1683 (0.12%)**
Colitis † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Constipation † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Crohn's disease † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Diarrhoea † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Gastritis † 1	
# participants affected / at risk	**4/1683 (0.24%)**
Gastrointestinal haemorrhage † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Haemorrhoids † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Pancreatitis † 1	

# participants affected / at risk	1/1683 (0.06%)
Peritonitis † 1	
# participants affected / at risk	1/1683 (0.06%)
Proctitis † 1	
# participants affected / at risk	1/1683 (0.06%)
Vomiting † 1	
# participants affected / at risk	1/1683 (0.06%)
General disorders	
Catheter thrombosis † 1	
# participants affected / at risk	1/1683 (0.06%)
Death † 1	
# participants affected / at risk	1/1683 (0.06%)
Local swelling † 1	
# participants affected / at risk	1/1683 (0.06%)
Malaise † 1	
# participants affected / at risk	3/1683 (0.18%)
Non-cardiac chest pain † 1	
# participants affected / at risk	5/1683 (0.30%)
Pain † 1	
# participants affected / at risk	3/1683 (0.18%)
Pyrexia † 1	
# participants affected / at risk	9/1683 (0.53%)
Hepatobiliary disorders	
Biliary colic † 1	
# participants affected / at risk	1/1683 (0.06%)

Cholelithiasis † 1	
# participants affected / at risk	**6/1683 (0.36%)**
Hepatitis † 1	
# participants affected / at risk	**2/1683 (0.12%)**
Hyperbilirubinaemia † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Liver disorder † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Immune system disorders	
Hypersensitivity † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Infections and infestations	
Abdominal infection † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Acute tonsillitis † 1	
# participants affected / at risk	**2/1683 (0.12%)**
Appendicitis † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Bacterial infection † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Bronchitis † 1	
# participants affected / at risk	**2/1683 (0.12%)**
Bronchopneumonia † 1	
# participants affected / at risk	**1/1683 (0.06%)**

Catheter related infection † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Catheter site infection † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Cellulitis † 1	
# participants affected / at risk	**2/1683 (0.12%)**
Diarrhoea infectious † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Ear infection † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Epstein-Barr virus infection † 1	
# participants affected / at risk	**3/1683 (0.18%)**
Escherichia bacteraemia † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Gastroenteritis † 1	
# participants affected / at risk	**3/1683 (0.18%)**
Gastrointestinal infection † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Hepatitis C † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Influenza † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Liver abscess † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Necrotising fasciitis † 1	

# participants affected / at risk	1/1683 (0.06%)
Osteomyelitis † 1	
# participants affected / at risk	2/1683 (0.12%)
Otitis media acute † 1	
# participants affected / at risk	1/1683 (0.06%)
Parvovirus infection † 1	
# participants affected / at risk	1/1683 (0.06%)
Perianal abscess † 1	
# participants affected / at risk	1/1683 (0.06%)
Pharyngitis † 1	
# participants affected / at risk	1/1683 (0.06%)
Pharyngitis streptococcal † 1	
# participants affected / at risk	1/1683 (0.06%)
Pneumonia † 1	
# participants affected / at risk	4/1683 (0.24%)
Pyelonephritis † 1	
# participants affected / at risk	1/1683 (0.06%)
Respiratory tract infection † 1	
# participants affected / at risk	2/1683 (0.12%)
Rhinitis † 1	
# participants affected / at risk	1/1683 (0.06%)
Sepsis † 1	
# participants affected / at risk	1/1683 (0.06%)
Tonsillitis † 1	
# participants affected / at risk	1/1683 (0.06%)

Upper respiratory tract infection † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Viral infection † 1	
# participants affected / at risk	**5/1683 (0.30%)**
Injury, poisoning and procedural complications	
Clavicle fracture † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Comminuted fracture † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Femur fracture † 1	
# participants affected / at risk	**2/1683 (0.12%)**
Forearm fracture † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Haemolytic transfusion reaction † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Post-traumatic pain † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Road traffic accident † 1	
# participants affected / at risk	**2/1683 (0.12%)**
Spinal fracture † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Suture rupture † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Thermal burn † 1	
# participants affected / at risk	**1/1683 (0.06%)**

Tibia fracture † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Upper limb fracture † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Investigations	
Alanine aminotransferase increased † 1	
# participants affected / at risk	**2/1683 (0.12%)**
Blood calcium increased † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Blood creatinine increased † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Cardiovascular evaluation † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Protein urine present † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Serum ferritin increased † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Transaminases increased † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Metabolism and nutrition disorders	
Hyperglycaemia † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Hypocalcaemia † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Hypoglycaemic seizure † 1	

# participants affected / at risk	1/1683 (0.06%)
Musculoskeletal and connective tissue disorders	
Arthralgia † 1	
# participants affected / at risk	1/1683 (0.06%)
Back pain † 1	
# participants affected / at risk	1/1683 (0.06%)
Fistula † 1	
# participants affected / at risk	1/1683 (0.06%)
Osteonecrosis † 1	
# participants affected / at risk	1/1683 (0.06%)
Pain in extremity † 1	
# participants affected / at risk	1/1683 (0.06%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Benign neoplasm of thymus † 1	
# participants affected / at risk	1/1683 (0.06%)
Hepatic neoplasm malignant recurrent † 1	
# participants affected / at risk	1/1683 (0.06%)
Non-small cell lung cancer † 1	
# participants affected / at risk	1/1683 (0.06%)
Nervous system disorders	
Convulsion † 1	
# participants affected / at risk	1/1683 (0.06%)
Headache † 1	
# participants affected / at risk	2/1683 (0.12%)
Migraine † 1	

# participants affected / at risk	1/1683 (0.06%)
Paraesthesia † 1	
# participants affected / at risk	1/1683 (0.06%)
Spinal cord compression † 1	
# participants affected / at risk	1/1683 (0.06%)
Pregnancy, puerperium and perinatal conditions	
Pregnancy † 1	
# participants affected / at risk	5/1683 (0.30%)
Psychiatric disorders	
Anxiety † 1	
# participants affected / at risk	1/1683 (0.06%)
Depression † 1	
# participants affected / at risk	1/1683 (0.06%)
Suicide attempt † 1	
# participants affected / at risk	1/1683 (0.06%)
Renal and urinary disorders	
Calculus ureteric † 1	
# participants affected / at risk	1/1683 (0.06%)
Nephrotic syndrome † 1	
# participants affected / at risk	1/1683 (0.06%)
Renal colic † 1	
# participants affected / at risk	2/1683 (0.12%)
Renal failure † 1	
# participants affected / at risk	2/1683 (0.12%)

Urethral stenosis † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Urinary retention † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Reproductive system and breast disorders	
Haemorrhagic ovarian cyst † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Uterine disorder † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Respiratory, thoracic and mediastinal disorders	
Adenoidal hypertrophy † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Asthma † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Dyspnoea † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Epistaxis † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Hypoxia † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Pleural effusion † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Pneumonitis † 1	
# participants affected / at risk	**1/1683 (0.06%)**

Pulmonary embolism † 1	
# participants affected / at risk	**2/1683 (0.12%)**
Skin and subcutaneous tissue disorders	
Erythema multiforme † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Pigmentation disorder † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Rash † 1	
# participants affected / at risk	**5/1683 (0.30%)**
Rash maculo-papular † 1	
# participants affected / at risk	**2/1683 (0.12%)**
Swelling face † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Urticaria † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Surgical and medical procedures	
Uterine dilation and curettage † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Vascular disorders	
Deep vein thrombosis † 1	
# participants affected / at risk	**1/1683 (0.06%)**
Hypotension † 1	
# participants affected / at risk	**1/1683 (0.06%)**

† 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	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
All Participants	Deferasirox was administered orally once a day, 30 minutes prior to breakfast. Dosage was based on participant's body weight. Tablets were dispersed in water, orange or apple juice.

Other Adverse Events

	All Participants
Total, other (not including serious) adverse events	
# participants affected / at risk	**85/1683 (5.05%)**
Skin and subcutaneous tissue disorders	
Rash † 1	
# participants affected / at risk	**85/1683 (5.05%)**

† 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:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided

Responsible Party:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00235391 History of Changes
Other Study ID Numbers:	**CICL670A2203**
Study First Received:	October 6, 2005
Results First Received:	December 17, 2010
Last Updated:	June 3, 2011
Health Authority:	United States: Food and Drug Administration