Chelova™ FCT

Deferasirox INN

Jenphar Bangladesh | جـنـفـار بنغلاديش

Composition:
Chelova™ 180 FCT Tablet: Each film coated tablet contains Deferasirox INN 180 mg.
Chelova™ 360 FCT Tablet: Each film coated tablet contains Deferasirox INN 360 mg.

Pharmacology:
Deferasirox is an orally active chelator that is highly selective for iron. It is a tridentate ligand that binds iron with high affinity in a 2:1 ratio. Deferasirox promotes excretion of iron, primarily in the faeces. Deferasirox has low affinity for zinc and copper, and does not cause constant low serum levels of these metals. In an iron balance metabolic study in iron overloaded adult thalassaemia patients, the bioavailability of Deferasirox film coated tablets was 36% greater than with Deferasirox tablets for oral suspension.

Indication:
Chronic Iron Overload due to Blood Transfusions (Transfusional Iron Overload) ≥2 years of age. Treatment of Chronic Iron Overload in Non-Transfusion-Dependent Thalassemia Syndromes ≥10 years of age.

Dose & Administration:
Administration:
Swallow Chelova™ FCT once daily with water or other liquids, preferably at the same time each day. Chelova™ FCT should be taken on an empty stomach or with a light meal. Do not take Chelova™ FCT with aluminum-containing antacid products. For patients who have difficulty swallowing whole tablets, Chelova™ FCT may be crushed and mixed with soft foods (e.g., yogurt or applesauce) immediately prior to use and administered orally.
For patients who are currently on chelation therapy with Chelova™ Dispersible Tablets and converting to Chelova™ FCT, the dose should be about 30% lower, rounded to the nearest whole tablet.

	Chelova™ Dispersible Tablet	Chelova™ FCT
Transfusion-Dependent Iron Overload		
Starting Dose	20 mg/kg/day	14 mg/kg/day
Titration Increments	5-10 mg/kg	3.5-7 mg/kg
Maximum Dose	40 mg/kg/day	28 mg/kg/day
Non-Transfusion-Dependent Thalassemia Syndromes		
Starting Dose	10 mg/kg/day	7 mg/kg/day
Titration Increments	5-10 mg/kg	3.5-7 mg/kg
Maximum Dose	20 mg/kg/day	14 mg/kg/day

Dose Adjustment:
Patients with Hepatic Impairment: Mild (Child-Pugh A) Hepatic Impairment: No dose adjustment is necessary. Moderate (Child-Pugh B) Hepatic Impairment: Reduce the starting dose by 50%. Severe (Child-Pugh C) Hepatic Impairment: Avoid Chelova™ FCT or Chelova™ Dispersible Tablet.
Patients with Renal Impairment: Do not use Chelova™ FCT or Chelova™ Dispersible Tablet in adult or pediatric patients with eGFR less than 40 mL/min/1.73 m^2. For patients with renal impairment (eGFR 40-60 mL/min/1.73 m^2), reduce the starting dose by 50%. Exercise caution in pediatric patients with eGFR between 40 and 60 mL/minute/1.73 m^2. If treatment is needed, use the minimum effective dose and monitor renal function frequently. Chelova™ FCT or Chelova™ Dispersible Tablet is contraindicated in patients with eGFR less than 40 mL/min/1.73 m^2 .
Transfusional Iron Overload: If the serum creatinine increases by 33% or more above the average baseline measurement, repeat the serum creatinine within 1 week, and if still elevated by 33% or more, reduce the dose by 7 mg/kg.
Non-Transfusion-Dependent Thalassemia Syndromes: If the serum creatinine increases by 33% or more above the average baseline measurement, repeat the serum creatinine within 1 week, and if still elevated by 33% or more, interrupt therapy if the dose is 3.5 mg/kg, or reduce by 50% if the dose is 7 or 14 mg/kg.

Contra-indication:
- *Estimated GFR less than 40 mL/min/1.73 m^2*
- *Poor performance status*
- *High-risk myelodysplastic syndromes*
- *Advanced malignancies*
- *Platelet counts less than 50 x 10^9/L*
- *Known hypersensitivity to deferasirox or any component of Deferasirox FCT*

Warning & precaution:
- *Acute Kidney Injury:* Monitor renal function during Deferasirox therapy and reduce dose or interrupt therapy for toxicity.
- *Hepatic Toxicity:* Monitor hepatic function. Reduce dose or interrupt therapy for toxicity.
- *Fatal and Nonfatal Gastrointestinal (GI) Bleeding, Ulceration, and Irritation:* Risk may be greater in patients who are taking Deferasirox in combination with drugs that have known ulcerogenic or hemorrhagic potential.
- *Bone Marrow Suppression:* Neutropenia, agranulocytosis, worsening anemia, and thrombocytopenia, including fatal events; monitor blood counts during Deferasirox therapy.
- *Age-related Risk of Toxicity:* Monitor elderly and pediatric patients closely for toxicity.

Side effects:
Common: Abdominal pain, Diarrhea, Nausea, Vomiting, Rash, Elevated Liver Enzyme and Creatinine.
Rare: Gastritis, Edema, Sleep disorder, Pigmentation disorder, Dizziness, Anxiety, Maculopathy, Cholelithiasis, Pyrexia and Fatigue.

Use In Special Population:
Pregnancy: There are no studies with the use of Deferasirox in pregnant women to inform drug-associated risks.
Lactation: No data are available regarding the presence of Deferasirox or its metabolites in human milk, the effects of the drug on the breastfed child, or the effects of the drug on milk production.
Renal Impairment: Deferasirox can cause glomerular dysfunction, renal tubular toxicity, or both, and can result in acute renal failure.
Hepatic Impairment: Avoid use in patients with severe (Child-Pugh C) hepatic impairment.

Drug interaction:
Aluminum-containing antacid preparations: Do not take Deferasirox with aluminum-containing antacid preparations. Deferasirox increases the exposure of repaglinide. Consider repaglinide dose reduction and monitor blood glucose levels. Avoid the use of Deferasirox with theophylline as theophylline levels could be increased. Deferasirox increases exposure of busulfan.

Overdose:
An erroneously administered single dose of 90 mg/kg led to Fanconi syndrome, which resolved after treatment. There is no specific antidote for Deferasirox.

Storage:
Store in a cool and dry place below 30°C, protect from light & moisture. Keep the medicine out of reach of children.

Packing:
Chelova™ 180 FCT Tablet: Each box contains 5 X 6's tablets in Alu-Alu blister pack.
Chelova™ 360 FCT Tablet: Each box contains 5 X 6's tablets in Alu-Alu blister pack.

Manufactured by:
Jenphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh.

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