Defera™
Deferiprone

Jenphar Bangladesh | جنفار بنغلاديش

Composition:
Defera 500 mg Tablet: Each film coated tablet contains Deferiprone INN 500 mg.

Pharmacology:
Defera is a chelating agent with an affinity for ferric ion (iron III). Deferiprone binds with ferric ions to form neutral complexes that are stable over a wide range of pH values. Deferiprone has a lower binding affinity for metal ions such as copper, aluminum, zinc and ferrous ions (iron II) than for ferric ions.

Indication:
Defera (deferiprone) is an iron chelator indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. Approval is based on a reduction in serum ferritin levels.

Dose & administration:
Starting Dose: The recommended initial dose of **Defera** is 25 mg/kg to 33 mg/kg body weight, orally, three times per day, for a total daily dose of 75 mg/kg to 99mg/kg body weight.

Body Weight (kg)	Total daily dose (mg)	Dose (mg, three times/day)	Number of tablets (three times/day)
20	1500	500	1
30	2250	750	1.5
40	3000	1000	2
50	3750	1250	2.5
60	4500	1500	3
70	5250	1750	3.5
80	6000	2000	4
90	6750	2250	4.5

Contra-indication:
Hypersensitivity to the active ingredient or any of the excipients.
History of recurrent episodes of neutropenia.
History of agranulocytosis.
Pregnancy or breast-feeding.
Due to the unknown mechanism of deferiprone-induced neutropenia, patients must not take medicinal products known to be associated with neutropenia or those that can cause agranulocytosis.

Warning and precaution:
If infection occurs while on Defera, interrupt therapy and monitor the ANC more frequently. Defera can cause fetal harm. Women should be advised of the potential hazard to the fetus and to avoid pregnancy while on this drug.

Side effects:
Adverse events associated with the use of Defera may include- Chromaturia, Nausea, Vomiting, Abdominal pain, Alanine aminotransferase increased, Arthralgia & Neutropenia.

Use in specific populations:
In Pregnancy: Pregnancy Category D

Nursing Mothers: **Defera** is excreted in human milk and may adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug.

Pediatric Use: The safety and effectiveness of **Defera** tablets for pediatric patients have not been established.

Geriatric Use: Safety and effectiveness in elderly individuals have not been established. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Renal Impairment: **Defera** has not been evaluated in patients with renal impairment.

Hepatic Impairment: **Defera** has not been conclusively evaluated in patients with hepatic impairment.

Drug interaction:
Avoid concomitant use of deferiprone with other drugs known to be associated with neutropenia or agranulocytosis. It is recommended to allow at least a 4-hour interval between taking deferiprone and other medications (e.g., antacids), or supplements containing these polyvalent cations.
Administration of deferiprone with food in healthy volunteers decreased the Cmax of deferiprone by 38% and the AUC by 10%. deferiprone can be taken with or without food.

Overdose:
No cases of acute overdose have been reported. There is no specific antidote to **Defera** overdose.

Storage Condition:
Store in a cool & dry place below 30^0C, protect from light. Keep out of the reach of children.

Packaging:
Defera 500 mg Tablet: Each box contains 50 film coated tablets and one packet silica gel in a sealed HDPE container.

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

12001844 Ver.: 01