

Hemoron™

Sodium Ferredetate

Composition

Each 5 ml of oral solution contains 207.5 mg of Sodium Ferredetate BP equivalent to 27.5 mg of Elemental Iron.

Pharmacology

Sodium Ferredetate is not an iron salt as it contains iron in an un-ionised form. In this compound the iron is "insulated" or "sequestered" with the sodium salt of Ethylenediamine Tetra-Acetic Acid (EDTA) to form a chelate so it does not discolor teeth. The iron chelate is split within the gastro-intestinal tract and releases elemental iron.

Post-absorption distribution of elemental iron is as follows: 60% to 70% is incorporated into haemoglobin and most of the remainder is present in storage forms, either as ferritin or haemosiderin, in the reticulo-endothelial system and to a lesser extent, hepatocytes. A further 4% is present in myoglobin and haeme-containing enzymes, or bound to transferrin in plasma.

EDTA is poorly absorbed and passes through the body unchanged after reaching the bloodstream.

Indication

Hemoron™ is an oral solution for adults, children and babies to treat iron deficiency anemia caused by too little iron in the body. The form of iron used in this product means that it is less likely to cause stomach upsets than other iron-containing medicines, and will not discolor teeth. It is indicated for:

- Iron Deficiency Anemia (especially children)
- Pregnant women when other forms of oral iron may not be well tolerated
- People who have become anemic as a result of having rheumatoid arthritis.

Dosage and Administration

Treatment of Anemia:

Adults and Elderly (over 65 years): 5 to 10 ml 3 times daily

Children: 3 to 6 mg/kg (max 200 mg) of elemental iron in 2-3 divided doses

Prevention of Anemia:

Babies of low-birth weight who are solely breast-fed: 5 mg of elemental iron daily.

A higher dose up to 2 mg/kg of elemental iron daily as given by healthcare professional may be required for exclusively breast-fed babies.

Babies (6 to 24 months): 2.5 ml daily

Children (2 to 5 years): 5 ml daily

Children (6 to 11 years): 5-10 ml daily

Adolescents: 10 ml daily

Contraindication

Hemoron™ is contraindicated in patients with a history of:

- Hypersensitivity to the active substance or to any of the excipients.
- Haemochromatosis, haemosiderosis and other Iron overload syndromes
- Receiving repeated blood transfusions

Warning and Precaution

Care should be taken in patients with haemolytic anaemia, iron-storage or iron-absorption diseases or existing gastrointestinal diseases. Iron preparations color the faeces black, which may interfere with tests used for detection of occult blood in the stools. Prolonged or excessive use in children may lead to toxic accumulation.

Side effects

Allergic reactions: e.g. itchy skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

Use in Pregnancy and Lactation

Administration of drugs during the 1st trimester of pregnancy requires careful assessment of potential risks versus benefits to be gained. No adverse events associated with Hemoron™ administration during pregnancy and lactation have been reported.

Drug Interactions

Avoid concomitant administration of oral iron with dimercaprol (formation of toxic compounds).

Iron reduces the absorption of penicillamine, mycophenolate, fluoroquinolones, levodopa, carbidopa, thyroxine and bisphosphonates. Administration of oral iron may reduce the hypotensive effect of methyldopa. Iron and tetracyclines reduce the absorption of each other. Iron and zinc reduce the absorption of each other.

Overdose

Initial symptoms of iron overdosage include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycaemia and metabolic acidosis may occur.

Storage Condition

Store below 25°C. Protect from light. Keep all medicines out of reach of children. Once opened the product should be used within 3 months.

How Supplied

Each pack contains 100 ml Oral Solution in a PET bottle.

Manufactured by:



SQUARE
PHARMACEUTICALS PLC.
Salgaria, Pabna, Bangladesh

TM - Trade Mark