NEW ZEALAND DATA SHEET

FERODAN

1. Product Name

FERODAN, 30 mg/mL, oral solution.

2. Qualitative and Quantitative Composition

Each mL oral solution contains 30 mg of ferrous sulfate heptahydrate (equivalent to 6 mg elemental iron).

Excipients with known effects: sucrose, sodium benzoate, sodium bisulfite and sorbitol.

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

FERODAN is a syrupy liquid with a fruity odour. The colour of FERODAN may vary from bluish green to very light yellow to gold. Colour variations within this range will not affect the effectiveness of the product.

4. Clinical Particulars

4.1 Therapeutic indications

Iron deficiency anaemia

4.2 Dose and method of administration

Dose

Children 0-2 years: Use only on medical advice.

Children 2-6 years: Up to 5 mL daily (in three divided doses), for example, 2 mL in the morning, 1 mL at lunchtime and 2 mL at night.

Children 6-12 years: 5 – 20 mL daily (in three divided doses), for example, 5 mL three times daily.

Adults and children 12 years and over: 15 – 30 mL daily (in three divided doses), for example, 5-10 mL three times daily.

Method of administration

Shake well before use.

The absorption of FERODAN is optimised when taken on an empty stomach (one hour before meals or three hours after a meal). Certain food, drinks and medicine can affect iron absorption (see section 4.5)

Treatment should not be extended beyond 3 months without review.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Paroxysmal nocturnal haemoglobinuria
- Haemosiderosis and haemochromatosis
- Active peptic ulcer
- Patients receiving repeated blood transfusions
- Regional enteritis and ulcerative colitis
- Haemolytic anaemia
- Oral and parenteral iron preparations should not be used concomitantly.

4.4 Special warnings and precautions for use

Some post-gastrectomy patients show poor absorption of iron.

Administer with caution in patients with haemoglobinopathies, iron storage or iron absorption disease, existing gastrointestinal disease.

Caution is advised when prescribing iron preparations to individuals with history of peptic ulcer, and inflammatory bowel disease, including regional enteritis and ulcerative colitis. Care should be taken in patients with intestinal strictures or diverticula. Duration of treatment should generally not exceed 3 months after correction of anaemia.

Patients suffering from iron overload are particularly susceptible to infection. Treatment of iron overload should be with caution.

Because anaemia due to combined iron and Vitamin B12 or folate deficiencies may be microcytic in type, patients with microcytic anaemia resistant to treatment with iron alone should be screened for Vitamin B12 or folate deficiency.

Long-term treatment with FERODAN solution may increase the risk of dental caries. Adequate dental hygiene must be maintained.

Since FERODAN solution contains sucrose, care must be taken when using in patients with diabetes mellitus.

Each 30 mL of FERODAN contains 5.3 g of sorbitol. Products containing sorbitol may have laxative effect or cause diarrhoea.

Patients with rare hereditary problems of galactose intolerance or fructose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicinal product.

4.5 Interaction with other medicines and other forms of interaction

Antibacterials: Iron and tetracyclines reduce the absorption of each other when administered concomitantly. Administration of iron preparations and tetracyclines should be separated by 2 to 3 hours.

Quinolones: Oral iron may reduce the absorption of quinolones (such as ciprofloxacin, norfloxacin, levofloxacin, moxifloxacin and ofloxacin). Administration of iron preparations and quinolones should be separated by at least 2 hours.

Chloramphenicol delays plasma iron clearance, incorporation of iron into red blood cells and interferes with erythropoiesis.

Antacids and mineral supplements: Compounds containing calcium, magnesium (including antacids and mineral supplements), bicarbonates, carbonates, oxalates or phosphates may impair the absorption of iron.

Administration of iron preparations with such compounds should be separated by at least 2 hours.

Bisphosphonates: The absorption of bisphosphonates is reduced when taken concurrently with iron preparations. Administration should be separated by at least 2 hours.

Cholestyramine: May bind iron to the gastrointestinal tract, thus preventing its absorption.

Dimercaprol: Avoid the concomitant use of iron with dimercaprol (see section 4.9).

Dopaminergics: Oral iron preparations may reduce the absorption of dopaminergics such as entacapone, levodopa and carbidopa/levodopa.

Food products: Absorption of iron is impaired by tea, coffee, milk, eggs and whole grains. Iron supplements should not be taken within one hour before or two hours after ingestion of these products. Absorption of iron salts is enhanced by ascorbic acid and meat.

Methyldopa: Oral iron preparations may antagonise the antihypertensive effect of methyldopa.

Mycophenolate mofetil: Oral iron preparations significantly reduce the absorption of mycophenolate mofetil.

Penicillamine: Oral iron preparations can reduce the absorption of penicillamine. Also, the absorption of iron is impaired by penicillamine.

Thyroid hormone: Oral iron reduces the absorption of levothyroxine (thyroxine) thus should be given at least 2 hours apart.

Trientine: The absorption of oral iron preparations is reduced by trientine. Administration should be separated by at least 2 hours.

Zinc: Iron preparations and zinc preparations can reduce the absorption of each other.

4.6 Fertility, pregnancy and lactation

Pregnancy

Use of any medicine during the first trimester of pregnancy should be avoided if possible. Thus, administration of iron during the first trimester requires evidence of iron deficiency. Prophylaxis of iron deficiency during the remainder of pregnancy is justified.

Breast-feeding

Ferrous salts are recommended for use in lactation, and no contraindications to such are known.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Although iron preparations are best absorbed on an empty stomach, they may be taken after food to reduce gastrointestinal side-effects.

Large doses may produce gastro-intestinal irritation, nausea, vomiting, epigastric pain, diarrhoea.

Constipation may be caused by continual administration, particularly in older patients, and may lead to faecal impaction.

Iron supplementation may cause the blackening of stool due to unabsorbed iron and is usually harmless. However, other side effects such as blood in stools, cramps or stomach pain should be investigated.

Hypersensitivity reactions have been reported. These range from rashes, sometimes severe to anaphylaxis.

Temporary discolouration of the teeth due to iron may be minimised through brushing. Placing FERODAN on the back of the tongue with a dropper or by using a straw may also help minimise teeth discolouration.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

Symptoms

Acute iron overdosage can be divided into four stages. In the first phase, which occurs up to 6 hours after oral ingestion, gastrointestinal toxicity, notably vomiting, nausea, abdominal pain and diarrhoea, predominates. The vomit and stools may be grey or black. Other effects may include cardiovascular disorders such as hypotension and tachycardia, metabolic changes including acidosis and hyperglycaemia, and CNS depression ranging from lethargy to coma. Patients with only mild to moderate poisoning do not generally pass this first phase. The second phase may occur at 6-24 hours after ingestion and is characterised by a temporary remission or clinical stabilisation. In the third phase gastrointestinal toxicity recurs together with shock, metabolic acidosis, convulsions, coma, hepatic necrosis and jaundice, hypoglycaemia, coagulation disorders, oliguria or renal failure, and pulmonary oedema. The fourth phase may occur several weeks after ingestion and is characterised by gastrointestinal obstruction and possibly late hepatic damage.

Overdosage of ferrous salts is particularly dangerous to young children.

Management

Treatment consists of gastric lavage followed by the introduction of 5 g desferrioxamine into the stomach. Serum iron levels should be monitored and in severe cases IV desferrioxamine should be given together with supportive and symptomatic measures as required. Gastric lavage with 5% sodium bicarbonate and saline cathartics (e.g. sodium sulfate 30 g for adults); milk and eggs with 5 g bismuth carbonate every hour as demulcents. Blood or plasma transfusion for shock, oxygen for respiratory embarrassment. Chelating agents (e.g. disodium calcium edetate) may be tried (500 mg/500 ml by continuous IV infusion). Dimercaprol should not be used since it forms a toxic complex with iron. Desferrioxamine is a specific iron chelating agent and severe acute poisoning in infants should always be treated with desferrioxamine at a dose of 90 mg/kg IM followed by 15 mg/kg per hour IV until the serum iron is within the plasma binding capacity.

For further advice on management of overdose please contact the National Poisons Information Centre (0800 POISON or 0800 764 766).

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antianemic preparations, iron preparations

ATC code: B03A A07

Ferrous sulfate is used in the treatment of iron deficiency anaemias.

Iron preparations have no intrinsic therapeutic activity except as a nutrient source: their use without evidence of iron deficiency, or reasonable expectations of its occurrence, is to be deprecated. Excessive iron is toxic, and haemochromatosis can result from chronic injection of iron preparations used as tonics, especially is individuals with undiagnosed blood disorders. Patients with chronic anaemia are particularly at risk from iron storage disease.

Recently a severe iron overload myopathy has been described in patients given prophylactic iron indiscriminately while receiving haemodialysis. Genetic factors probably contribute to the risk of iron overload.

It should be clear that although iron deficiency is easily treated, its detection does not constitute a complete diagnosis. Every effort should be made to determine why the patient has entered a state of negative iron balance. Attention should be given to hidden sources of haemorrhage (which may indicate serious urinary or gastrointestinal conditions) and the possibility of malabsorption of iron caused by latent disease of the small intestine.

5.2 Pharmacokinetic properties

Absorption

Iron is irregularly and incompletely absorbed from the gastrointestinal tract, the main sites of absorption being the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach or by dietary acids and is more readily affected when the iron is in the ferrous state or is part of the haem complex (haem-iron unit). Absorption is also increased in conditions of iron deficiency or in the fasting state but is decreased if the body stores are overloaded. Only about 5-15% of the iron ingested in food is normally absorbed.

Distribution

Following absorption, the majority of iron is bound to transferrin and transported to the bone marrow where it is incorporated into haemoglobin. The remainder is stored within ferritin or haemosiderin or is incorporated into myoglobin with smaller amounts occurring in haem-containing enzymes or in plasma bound to transferrin.

Elimination

Only very small amounts are excreted as the body reabsorbs the iron after the haemoglobin has broken down.

6. Pharmaceutical Particulars

6.1 List of excipients

FERODAN oral solution 30 mg/mL also contains

- Sucrose
- Sorbitol
- Glycerine
- Citric acid
- Sodium benzoate
- Sodium bisulfite
- Purified water
- Lemon flavour (containing ethanol, essential oils and natural and artificial flavours)
- Strawberry flavour (containing propylene glycol, acetic acid and natural and artificial flavours)
- Pineapple flavour (containing propylene glycol, polysorbate 80, natural and artificial flavours)

Contains sugars, benzoates, sulfites and sorbitol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store at or below 25°C.

Keep the bottle tightly closed and ensure that the child resistant cap is engaged after use.

6.5 Nature and contents of container

Bottles of 250 mL and 500 mL.

Not all pack types and sizes may be marketed.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Medicines Schedule

Pharmacy only medicine

8. Sponsor Details

Viatris Ltd
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AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

9. Date of First Approval

31 March 2005

10. Date of Revision of the Text

13 September 2023

Summary table of changes

Section	Summary of new information
Header	Updated sponsor name and logo.
2	Addition of excipients with known effects
4.4	Addition of warnings associated with sorbitol
6.1	Added allergen statement as ‘Contains sugars, benzoates, sulfites and sorbitol.

6.1, 6.4	Minor editorial change; deleted allergen statement ‘gluten and lactose free.’
8	Updated sponsor details.
10	Updated date of text revision.