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).

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.

Patients receiving repeated blood transfusions; concomitant parenteral iron; haemochromatosis and other iron overload syndromes.

Blood disorders (other than iron deficiency anaemia; e.g. paroxysmal nocturnal haemoglobinuria, haemosiderosis, other anaemias) and inability to absorb iron (e.g. due to active peptic ulcer, regional enteritis, ulcerative colitis).

4.4 **Special warnings and precautions for use**

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

Before starting treatment, it is important to exclude any underlying cause of the anaemia (e.g. gastric erosion, colonic carcinoma).

Some post-gastrectomy patients show poor absorption of iron. Care is required when treating patients with iron deficiency anaemia who have treated or controlled peptic ulceration.

Duration of treatment of uncomplicated iron deficiency anaemia should not usually exceed 6 months (3 months after reversal of the anaemia has been achieved).

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.

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**

Concurrent administration with tetracyclines may impair absorption of both agents. The absorption of ciprofloxacin, norfloxacin, levofloxacin, moxifloxacin, ofloxacin, entacapone, mycophenolate and bisphosphonates is reduced by oral iron. Cholestyramine may bind iron to the gastrointestinal tract, thus preventing its absorption.

The absorption of iron salts is also decreased in the presence of antacids, preparations containing calcium, magnesium, phosphorus, trientine, or when taken with 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.

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

Oral iron antagonises hypotensive effect of methyldopa.

The absorption of levodopa and penicillamine may be reduced when given with iron salts.

Absorption of iron salts is enhanced by ascorbic acid and meat.
Avoid the concomitant use of iron with dimercaprol (see section 4.9).

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

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

4.6 Fertility, pregnancy and lactation

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

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.

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 demulcients. 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 in 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 an iron storage disease.

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 a state of negative iron balance. Attention should be given to hidden sources of haemorrhage (which may indicate serious urinary or gastrointestinal conditions) and also 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 the 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 decreased if the body stores are overloaded. About 5-15% of the iron ingested in food is 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 bisulphite
- 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)

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years

6.4 Special precautions for storage
Store below 25°C.

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

FERODAN is gluten and lactose free.

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

Mylan New Zealand Ltd
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AUCKLAND
Telephone 09-579-2792

9. Date of First Approval

31 March 2005

10. Date of Revision of the Text

6 August 2019

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