SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

IRONORM DROPS

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:-

Ferrous Sulfate BP 125mg
(equivalent to 25mg Iron per ml).

Excipients with known effect
Sodium Metabisulfite 0.100 g/ml
Sorbitol Solution 432 mg/ml
Propylene Glycol 130 mg/ml
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral drops, solution

A green to yellow syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For prevention and treatment of iron deficiency anaemias.

4.2 Posology and method of administration

Method of administration
Oral

Posology

Prophylactic:

A daily dose of 5 mg of elemental iron as prophylactic iron supplementation for babies of low birth weight who are solely breast-fed is recommended. Higher doses up to 2mg/kg of elemental iron per day might be needed to cover the needs of

growing exclusively breastfed infants. Supplementation is started 4-6 weeks after birth and continued until mixed feeding is established.

Older infants and children to 6 years: 0.5 – 1.2 ml per day (12.5 – 30 mg elemental iron).

Older children: 2.4 ml per day (60 mg elemental iron).

Adults and Elderly: 2.4 – 4.8 ml per day (60 – 120 mg of elemental iron)

Therapeutic:

Paediatric: 0.12ml to 0.24ml (3mg – 6mg elemental iron) per kg body weight, up to a maximum of 8ml (200mg elemental iron) given daily in two or three divided doses.

Adults: 4.0 ml once or twice per day (100 – 200 mg elemental iron)

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Contraindicated for use in patients with the following conditions: Haemosiderosis and haemocromatosis, Active peptic ulcer, Repeated blood transfusion, Regional enteritis and ulcerative colitis, Haemolytic anaemias.

4.4 Special warnings and precautions for use

- Patients post-gastrectomy have poor absorption of iron.
- Caution is advised when prescribing iron preparations to individuals with history of peptic ulcer.
- Duration of treatment should generally not exceed 1-2 months after end of pregnancy.
- Coexisting deficiency of dietary vitamin B12 should be ruled out since combined deficiency produces microcytic blood film.
- Care should be taken in patients with intestinal strictures and diverticulae.
- Caution is required in the elderly where there is an increased risk of faecal impaction.

- The label will state “Important warning: Contains iron. Keep out of the reach and sight of children, as overdose may be fatal”. This will appear on the front of the pack within a rectangle in which there is no other information.

- Metabisulfite can cause allergic reactions (such as skin rash and fluid retention) and bronchospasm (asthma-like difficulty in breathing) in susceptible individuals.

- This medicine contains 2075mg of sorbitol in each 4.8ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

- This medicine contains 623 mg propylene glycol in each 4.8ml. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

4.5. Interactions with other medicinal products and other forms of interaction

- Iron and tetracyclines interfere with absorption of each other.
- Absorption of iron is impaired by penicillamine, antacids, cholestyramine, tea, eggs and milk.
- Chloramphenicol delays plasma clearance of iron, incorporation of iron into red blood cells by interfering with erythropoiesis.

4.6 Fertility, pregnancy and lactation

Pregnancy

Administration of drugs during the first trimester of pregnancy requires careful assessment of potential risks versus benefits to be gained and Ironorm should not be administered unless clearly indicated.

4.7 Effects on ability to drive and use machines

Ironorm Drops has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Anorexia, nausea, vomiting, gastrointestinal discomfort, reversible dental staining, constipation, diarrhoea, dark stools and allergic reactions. The product contains metabisulfite as a preservative which can precipitate allergic reactions and bronchospasm in susceptible individuals.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme:
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9. Overdose

Iron overdosage is an acute emergency requiring urgent medical attention. An acute intake of 75mg/Kg of elemental iron is considered extremely dangerous in young children. Serum iron levels should be monitored.
Symptoms and signs include abdominal pain, diarrhoea and vomiting (haematemesis is a possibility) within 1 - 2 hours, followed by cardiovascular collapse and coma in some patients. Recovery follows this phase and in some patients this continues; in others, deterioration occurs in about 15 hours characterised by diffuse vascular congestion, pulmonary oedema, convulsion, hypothermia, renal failure, shock, metabolic acidosis, coagulopathy and/or hypoglycaemia. Treatment consists of supportive and symptomatic measures. Vomiting should be induced if the patient presents early and gastric lavage should be considered using a solution of desferrioxamine. Parenteral injection of 2g desferrioxamine should be given IV or IM and 5g of desferrioxamine in 50 - 100ml of fluid may also be left in the stomach.
Recovery may be complicated by long term effects such as hepatic necrosis, toxic encephalitis and CNS damage, and pyloric stenosis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Iron Preparations, Iron bivalent, oral preparations, ferrous sulfate.

ATC Code: B03AA07

5.2. Pharmacokinetic properties

The active is in solution and readily absorbed as the ferrous salt.

5.3. Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium Edetate,
Ascorbic Acid,
Sodium Metabisulfite,
Purified Water,
Propylene Glycol,
Orange Oil Soluble,
Sorbitol Solution 70%.

6.2 Incompatibilities

None

6.3. Shelf life

36 months.

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

15ml Type III Glass dropper bottle with an 18mm white HDPE child resistant cap, supplied with a calibrated oral syringe 1ml.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Wallace Manufacturing Chemists Ltd.

Wallace House

51-53 Stert Street

Abingdon

Oxfordshire OX14 3JF

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL00400/0010R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

18 September 1990 / 23 January 1996

10 DATE OF REVISION OF THE TEXT

17/06/2022