SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ironorm Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:
Ferrous Sulfate, dried 195 mg
Folic Acid 1.7 mg
Thiamine Hydrochloride (Vit B1) 1 mg
Riboflavine (Vit B2) 2 mg
Ascorbic Acid (Vit C) 15 mg
Nicotinamide 10 mg

Excipients with known effect
Soya Oil, Sorbitol Solution.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft
Maroon coloured soft, gelatin capsules

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The treatment of iron and vitamin deficiency states.

4.2 Posology and method of administration

One capsule to be taken by mouth three times a day with meals.

4.3 Contraindications

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

Hypersensitivity to peanut or soya.

4.4 Special warnings and precautions for use

Use with caution in the presence of Haemochromatosis, Haemolytic Anaemias and Haemoglobinopathies.

The label will state "Important warning: Contains iron. Keep out of the sight and reach 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.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Ironorm capsules contain soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

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 or milk. Chloramphenicol delays plasma clearance of iron.

4.6 Fertility, pregnancy and lactation

As with all medicines, Ironorm preparations should only be administered where potential benefit exceeding any risk has been demonstrated, especially during the first trimester of pregnancy.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

System Organ Class	Very Common (≥1/10)	Common ≥1/100, < 1/10	Uncommon ≥1/1,000, <1/100	Rare ≥1/10,000, <1/1000	Very Rare <1/10,000	Not known (cannot be estimated from available data)
Gastrointestinal Disorders						Nausea and vomiting Gastrointestinal discomfort Constipation Diarrhoea Discoloured (dark) stools
Immune System Disorders						Allergic reactions

System Organ Class	Very Common (≥1/10)	Common ≥1/100, < 1/10	Uncommon ≥1/1,000, <1/100	Rare ≥1/10,000, <1/1000	Very Rare <1/10,000	Not known (cannot be estimated from available data)
Metabolism and Nutrition disorders						Anorexia

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

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 after 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 2gm desferrioxamine should be given IV or IM and 5gm 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 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antianemic Preparations:
ATC code: B03AE02.

Iron and Multivitamins. Multivitamin Supplement

5.2 Pharmacokinetic properties

Soft gelatine capsule complies with BP disintegration test and all actives are bioavailable.

5.3 Preclinical safety data

Not applicable

6.1 List of excipients

Vegetable Oil, Fat Mix, Lecithin, Coat, Gelatin, Glycerin, Sorbitol Solution, Potassium Sorbate, Black Iron Oxide, Carmine Red, Yellow Iron Oxide, Titanium Dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Keep in a cool, dry place.

6.5 Nature and contents of container

Glass vials of 25 capsules. Glass jars of 100 capsules

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

PL 0400/5016R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1 May 1972

10 DATE OF REVISION OF THE TEXT

23/05/2016