

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ironorm Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains: -

Iron and Ammonium Citrate BP'73	250.00 mg
Thiamine Hydrochloride BP	0.50 mg
Riboflavine BP	0.25 mg
Pyridoxine Hydrochloride BP	0.125 mg
Nicotinamide BP	3.75 mg
Calcium Pantothenate USP	0.125 mg
Calcium Glycerophosphate BPC'63	10.75 mg
Sodium Glycerophosphate BPC'49	21.25 mg
Potassium Glycerophosphate BPC'63	1.75 mg
Manganese Glycerophosphate BPC'49	1.00 mg

3. PHARMACEUTICAL FORM

Oral Syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

As a supplement of Iron, Vitamins B and minerals in situations of special dietary need. Not suitable for correction of deficiency status.

4.2 Posology and method of administration

Oral

Adults: One 5ml spoonful daily

Children: Not recommended

4.3 Contraindications

- Hypersensitivity to any of the ingredients.
- Haemosiderosis and haemoglobinopathies.
- Haemolytic anaemias.
- Unexplained anaemia.
- Renal failure.

4.4 Special warnings and special precautions for use

Administration of Ironorm Syrup may mask signs of occult blood loss.

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.

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, incorporation of iron into red blood cells by interfering with erythropoiesis.

The efficacy of L-Dopa is reduced by pyridoxine.

4.6 Pregnancy and lactation

Not recommended for use during the first trimester. Safe after the first trimester only when taken in recommended doses and if no other iron or calcium supplements are taken concurrently. Safe during lactation when used in recommended doses.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Constipation, diarrhoea, dark stools, nausea and gastric irritation. Allergic reactions may occasionally occur..

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.

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, convulsions, hypothermia, renal failure, shock, metabolic acidosis, coagulopathy and/or hypoglycaemia.

Treatment consists of supportive and symptomatic measures. Vomiting should be induced if 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

A supplement of iron, Vitamin B complex, and minerals in cases of special dietary need.

5.2 Pharmacokinetic properties

The absorption of iron salts from the gastro-intestinal tract varies widely with individuals. Unabsorbed iron will blacken the faeces. Peak plasma levels are usually reached in about 2 hours.

Vitamins of the B-complex are absorbed from the gastro intestinal tract and widely distributed in body tissues. Little is stored in the body and quantities in excess of body requirements are excreted in the urine.

The mineral salts of glycerophosphoric acid are readily absorbed from the gastro intestinal tract.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerin, Glycerophosphoric Acid, Dilute Hydrochloric Acid, Hydroxybenzoates (Methyl, Ethyl, Propyl and Butyl), Propylene Glycol, Flavouring (Orange Essence and Morella Cherry Essence), Sucrose, Caramel (E150), Potassium Sorbate and Water

6.2 Incompatibilities

Not Known

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store in a cool place.

6.5 Nature and contents of container

Glass bottle containing 150ml of Ironorm Syrup

6.6 Instructions for use/handling

None stated.

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 00400/5017R

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

18/01/2005

10 DATE OF REVISION OF THE TEXT

17/04/2009