Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Feospan Spansule 150 mg Modified Release Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each modified release capsule contains 150 mg dried ferrous sulphate (equivalent to 47 mg elemental iron).

Excipents: also contains sucrose 105.9 mg per capsule and sunset yellow (E110).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Modified release, hard capsule.
Modified release capsule containing red and green pellets in size no. 2 hard gelatin shells with clear bodies and ruby red caps.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the prevention of iron deficiency anaemia in adults at risk.

4.2 Posology and method of administration

Posology

Adults and children over 12 years:
Two capsules per day.

Elderly:
Dosage as above.

Children aged under 12 years:
Not recommended.

Method of Administration
Oral.

Alternatively the capsule may be opened and the pellets mixed with soft cold food but they must not be chewed or sucked.

Medical advice should be sought if symptoms do not improve after four weeks of use of this product as these symptoms may reflect an underlying disease process.

4.3 Contraindications

Do not use in patients with a known hypersensitivity to the active ingredient.

Individuals with haemochromatosis and iron overload syndrome.

4.4 Special warnings and precautions for use

The label will state:
“Important warning: Contains Iron. Keep out of 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.

Overdose may be fatal, particularly in children.

Side effects including nausea, diarrhoea and/or constipation may occur.

Prolonged or excessive use in children without medical supervision may lead to toxic accumulation.

This product should only be used in the prevention of iron deficiency anaemia diagnosed by laboratory testing under the supervision of a medical doctor.

Caution is advised in individuals with a family history of haemochromatosis or iron overload syndromes. It should be noted that these conditions may be under diagnosed.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Iron reduces the absorption of penicillamine by as much as two thirds, though the potential for interaction can be reduced by separating administration of each product by several hours. Iron compounds impair the bioavailability of quinolones, levodopa, carbidopa, methyldopa, thyroxine, bisphosphonates and possibly sulphasalazine.

Absorption of both iron and tetracycline are reduced if taken concomitantly, and likewise the absorption of concomitantly taken iron and zinc.

Aluminium hydroxide, calcium or magnesium containing compounds, including mineral supplements, and (bi)carbonates, oxalates, phosphates, silicates and alginate-rich preparations interact strongly with medicinal iron by the formation of insoluble complexes. Cholestyramine and iron may bind in the gut and therefore separating the dosing of these two compounds would be advisable.

Concurrent administration of antacids may reduce absorption of iron.

Some inhibition of iron absorption or bioavailability may occur if it is taken with trientine, tea, eggs, milk or coffee. Response to iron therapy may be delayed in patients receiving chloramphenicol. Neomycin may alter the absorption of iron.

Citrate, digestion products of meat, fructose, ascorbic acid and alcohol may enhance the bioavailability of iron.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Dark stools are usual during iron therapy, and nausea and other symptoms of gastrointestinal irritation, such as anorexia, vomiting, discomfort, constipation, and diarrhoea are sometimes encountered. Feospan Spansule Capsules are designed to reduce the possibility of gastrointestinal irritation. There have been rare reports of allergic reactions.

4.9 Overdose

Iron overdosage is dangerous, particularly in children and requires immediate attention. Treatment is necessary if more than 30 mg elemental iron per kilogram body weight has been ingested. In the first phase, 30 minutes to 6 hours after ingestion, symptoms may include abdominal pain, vomiting, diarrhoea and haematemesis, with in more severe cases, coma, convulsions and shock. Symptoms then abate, with either recovery, or within 12 hours after ingestion, deterioration. Symptoms can then include severe lethargy or coma, gastrointestinal haemorrhage, severe shock, metabolic acidosis, convulsions, jaundice, coagulation disorders, hypoglycaemia, renal failure and pulmonary oedema. These may last up to 48 hours after ingestion. In the last phase, 2 to 4 weeks after ingestion effects such as encephalopathy, hepatic necrosis and pyloric stenosis may occur. The sustained-release Spansule capsule presentation of ferrous sulphate may delay excessive absorption of iron and allow more time for initiation of appropriate countermeasures. Gastric lavage should be carried out in the early stages, or if this is not possible, vomiting should be induced. Give oral desferrioxamine (2 g for a child and 5 g for an adult) and demulcents. If serum iron levels at 4 hours or more post-ingestion are over 5 mg/l in a child, or 8 mg/l in an adult, or if the patient is in shock or coma, intramuscular or intravenous desferrioxamine should be used according to instructions for this product. Symptomatic and supportive measures should be given as required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The product is a haematinic for the prevention of iron deficiency.

5.2 Pharmacokinetic properties

The product is formulated to avoid iron release in the stomach where gastric irritation may be caused.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Talc
Heavy kaolin
Sucrose
Gelatin
Titanium dioxide (E171)
Red iron oxide (E172)
Povidone 30
Glycerol monostearate

White beeswax
Green lake (aluminium lakes of indigotine (E132), sunset yellow FCF (E110) and quinoline yellow (E104))

Hard Gelatin Capsule
Erythrosine (E127)
Patent blue V (E131)
Gelatin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

PVC-PVdC/aluminium blisters in packs of 15 and 30.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Intrapharm Laboratories Ltd.
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8 MARKETING AUTHORISATION NUMBER

PA 997/7/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1980

Date of last renewal: 01 April 2010

10 DATE OF REVISION OF THE TEXT

September 2012