Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fefol Spansule 150 mg/0.5 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) and 0.5 mg folic acid.

Excipients - contains Sucrose 105.0 mg per capsule.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Modified release hard capsules
Modified release capsule containing red, yellow and white pellets in size no.1 hard gelatin shells with clear bodies and transparent green caps.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Fefol is a haematinic with added folic acid used for the prophylaxis of iron and folic acid deficiency, after the first 13 weeks of pregnancy.

4.2 Posology and method of administration

Dosage:

Adults only:
1 capsule a day during pregnancy. Some pregnant patients may need a higher dose of iron because of dietary or other factors.

Children and elderly:
Not recommended.

Medical advice should be sought if symptoms do not improve after 4 weeks of use of this product as these symptoms may reflect an underlying disease process.

Method of Administration:
Oral.

4.3 Contraindications

Do not use in patients with a known hypersensitivity to any of the active ingredients.

Use in patients with anaemias of undiagnosed aetiology.

Individuals with haemochromatosis and iron overload syndromes.

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.

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.

Failure to respond to treatment may indicate other causes of anaemia and should be further investigated.

The folic acid content is unlikely to mask pernicious anaemia should this condition be present; pregnancy during pernicious anaemia is very rare.

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 interactions

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.

Folic acid supplementation may reduce serum anticonvulsant levels. Magnesium trisilicate and sulphasalazine may reduce the absorption of folic acid from the gut. Co-trimoxazole, sulphonamides, and aminopterin may interfere with the metabolism of folic acid.

Fluorouracil toxicity may occur in patients taking concurrent folic acid; this is consistent with the therapeutic use of folinic acid to increase the potency of fluorouracil.

The manufacturers of the antimetabolite raltitrexed claim folic acid could theoretically interfere with the action of raltitrexed.

4.6 Fertility, pregnancy and lactation

Fefol should not be used during the first trimester of pregnancy. Prophylaxis of iron and folate 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. Fefol Spansule Capsules are designed to reduce the possibility of gastrointestinal irritation. There have been rare reports of allergic reactions.

Immune system disorders
Frequency not known: anaphylactic reaction

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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 an oral iron and folic acid preparation for the prophylaxis of iron and folic acid deficiency during pregnancy.

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

No further information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Talc
Heavy kaolin
Sucrose
Gelatin
Titanium dioxide (E171)
Red iron oxide (E172)
Povidone
Glycerol monostearate
White beeswax
Calcium sulphate dihydrate
Quinoline yellow (E104)
Patent blue V (E131)

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/aluminium foil blister pack containing 15 or 30 capsules.

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

Intapharm Labs Ltd
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2305 Nicosia
Cyprus

8 MARKETING AUTHORISATION NUMBER

PA23101/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1April 1980

Date of last renewal: 1 April 2010

10 DATE OF REVISION OF THE TEXT

November 2020