

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fer In Sol 25mg/ml oral drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of liquid contains 125 mg of Ferrous Sulphate equivalent to 25 mg of available iron.
Also contains Sucrose 383.1 mg/ml, Sorbitol Solution (70%) 309.1 mg/ml and Ethanol 1.612 mg/ml.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral drops, solution.
A colourless or light bluish green to yellowish brown liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the prevention and treatment of iron deficiency anaemia.

4.2 Posology and method of administration

Neonates:
The use of Fer-in-Sol in neonates (infants less than 4 weeks of age) is not recommended.

Infants and Children:

Prevention: The usual dose is 0.3 to 0.6ml daily.

Treatment: The usual dose of elemental iron is 3 to 6 mg/kg (max. 200 mg) daily given in 2 to 3 divided doses. Use the syringe provided along with the table below.

Weight of Infant/Child	Dosage of Fer-in-Sol per day	Level of elemental iron Provided per day
3 to 4kg	2 x 0.3ml	15mg Fe
4 to 6kg	3 x 0.3ml	23mg Fe
7 to 9kg	2 x 0.6ml	30mg Fe
9 to 15kg	3 x 0.6ml	45mg Fe
> 15kg	2 x 1.5ml	75mg Fe

Doses should be given in water, fruit or vegetable juice.

Adults and the Elderly: Fer-In-Sol is not recommended for use in adults.

4.3 Contraindications

Use in patients with known hypersensitivity to any of the ingredients. Individuals with haemochromatosis and iron overload syndromes.

4.4 Special warnings and precautions for use

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

This product should be used with caution in patients with haemochromatosis and haemolytic anaemias. Caution is also advised in individuals with a family history of haemochromatosis or iron overload syndromes. It should be noted that these conditions may be underdiagnosed. Overdose may be fatal, particularly in children.

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

This preparation may cause temporary discoloration of the teeth and cause the faeces to be coloured black.

4.5 Interaction with other medicinal products and other forms of interaction

The absorption of iron salts is decreased in the presence of antacids, trientine, zinc and tetracyclines.

Iron salts diminish the absorption of tetracyclines, ciprofloxacin, levofloxacin, norfloxacin, ofloxacin, bisphosphates, zinc salts and penicillamine. It may also reduce the absorption of entacapone and levodopa.

Ferrous sulphate also reduces the hypotensive effect of methyldopa.

4.6 Fertility, pregnancy and lactation

Fer-in-Sol should not be taken in the first 13 weeks of pregnancy. If iron containing products are considered essential during the first 13 weeks of pregnancy they should only be taken under medical supervision. Prophylaxis of iron deficiency during the remainder of pregnancy is justified. No contraindications are known to use in lactation.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

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

Hypersensitivity reactions have been reported. These range from rashes, sometimes severe to anaphylaxis.

4.9 Overdose

Relatively small overdoses of iron can produce symptoms of toxicity (See 'Special Warnings and Special Precautions for Use'). Haemosiderosis may occur as a result of excessive oral therapy. In treating acute iron poisoning, speed is essential to block absorption of iron from the alimentary tract. Emesis or lavage should be considered and serum-iron concentrations may be an aid to estimating the severity of poisoning. Metabolic and cardiovascular disorders should be treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: B03AA07

Iron is an essential constituent of the body, being necessary for haemoglobin formation and for the oxidative processes of living tissues. The body contains about 4g of iron most of which is present as haemoglobin.

5.2 Pharmacokinetic properties

Iron is irregularly and incompletely absorbed from the gastro-intestinal tract, the main sites of absorption being the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach or by dietary acids and is more readily affected when the iron is in the ferrous state or is part of the haem complex (haem-iron). Absorption is also increased in conditions of iron deficiency or in the fasting state but is decreased if the body stores are overloaded.

Only about 5 to 15% of the iron ingested in food is normally absorbed. Apart from haemorrhage, iron is lost from the body in the faeces, urine, from skin and sweat, but the total loss is very small.

5.3 Preclinical safety data

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric Acid Anhydrous
Ethanol
Lemon Oil
Peppermint Oil
Sulphuric Acid
Sorbitol
Sucrose
Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Keep the bottle tightly closed.
Do not store above 25°C.

6.5 Nature and contents of container

30ml Type III Ph. Eur. amber glass bottle closed with polyethylene lined plastic (HDPE) “Clic-loc”-type closure with tamper evident security seal. One bottle is packed in a carton together with a calibrated oral syringe.

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

MEAD JOHNSON Nutrition
Middenkampweg 2
6545 CJ Nijmegen
The Netherlands

8 MARKETING AUTHORISATION NUMBER

PA 1751/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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