SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fersamal 140mg/5ml Syrup
Ferrous fumarate 140mg/5ml Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of syrup contains approximately 140mg ferrous fumarate BP (45mg elemental iron).

Excipients with Known effect:

Nipastat	5 mg/5ml
Liquid Glucose	4.2 g/5ml
Sucrose	251.67 mg/5ml
Sodium metabisulphite	7.6 mg/5ml

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylaxis and treatment of iron deficiency states.

For prophylaxis during pregnancy, a combination of iron and folic acid is usually recommended.

4.2 Posology and method of administration

Posology

Each 5 ml of Fersamal syrup contains 140 mg Ferrous Fumarate which approximates to 45 mg of elemental iron – section 2 SmPC.
Prevention of iron deficiency:
Adults and elderly:
Fersamal syrup one 5 ml spoonful twice a day.

Paediatric population
6-24 months of age: 12.5mg/day
2-5 years of age: 20-30mg/day
6-11 years of age: 30-60mg/day
Older children: 60mg/day

Premature infants: 5mg elemental iron per day. Iron supplementation in premature infants is only recommended in those of low birth weight who are solely breast fed. Higher doses up to 2mg/kg of elemental iron per day might be needed to cover the needs of growing exclusively breastfed infants. Supplementation should be commenced 4-6 weeks after birth and continued until mixed feeding is established.

Treatment of iron deficiency:
Adults and elderly:
Fersamal syrup two 5 ml spoonfuls twice a day
Paediatric population:
Full term infants and children: 3 to 6 mg elemental iron/Kg/day given in 2 to 3 divided doses. Total daily dose should not exceed 180 mg elemental iron.
Administration to infants and children should take place under medical advice.
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.
Method of administration: Oral

4.3 Contraindications

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

Known hypersensitivity to any of the ingredients of the product. Paroxysmal nocturnal haemoglobinuria. Haemosiderosis, haemochromatosis. Active peptic ulcer. Repeated blood transfusions. Regional enteritis and ulcerative colitis. Must not be used in anaemias other than those due to iron deficiency.

4.4 Special warnings and precautions for use

Some post-gastrectomy patients show poor absorption of iron. Care is required when treating patients with iron deficiency anaemia who have treated or controlled peptic ulceration.

Duration of treatment of uncomplicated iron deficiency anaemia should not usually exceed 6 months (3 months after reversal of the anaemia has been achieved).

Because anaemia due to combined iron and Vitamin B12 or folate deficiencies may be microcytic in type, patients with microcytic anaemia resistant to treatment with iron alone should be screened for Vitamin B12 or folate deficiency.

Paediatric population

Fersamal syrup should be kept out of the reach of children.

Long-term treatment with Fersamal syrup may increase the risk of dental caries. Adequate dental hygiene must be maintained. Since Fersamal syrup contains sugar, care must be exercised when using in patients with diabetes mellitus.

Fersamal Syrup contains:

Glucose: Patients with rare Glucose galactose malabsorption should not take this medicine.

Sucrose: Patients with rare hereditary problems of fructose intolerance, glucosegalactose 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, bisphosphonates, ciprofloxacin, entacapone, levodopa, levofloxacin, levothyroxine (thyroxine) (give at least 2 hours apart), moxifloxacin, mycophenolate, norfloxacin, ofloxacin, zinc. Absorption of both iron and antibiotic may be reduced if Fersamal 140mg/5ml is given with tetracycline. Absorption of oral iron is reduced by calcium salts, Magnesium salts (as magnesium trisilicate), Trientine.

Chloramphenicol delays plasma iron clearance, incorporation of iron into red blood cells and interferes with erythropoiesis. Some inhibition of iron absorption may occur if it is taken with cholestyramine, tea, eggs or milk.

Avoid concomitant use of iron with dimercaprol.

Oral iron antagonises hypotensive effect of methyldopa.

4.6 Fertility, pregnancy and lactation

Pregnancy

Ferrous fumarate can be used during pregnancy if clinically indicated.

Breastfeeding

No adverse effects of ferrous fumarate have been shown in breastfed infants of treated mothers. Ferrous fumarate tablets can be used during breast-feeding if clinically indicated.

4.7 Effects on ability to drive and use machines

Not relevant

4.8 Undesirable effects

The following adverse reactions are classified by system organ class and ranked under heading of frequency using the following convention:

Not known: frequency cannot be estimated from the available data

Gastrointestinal disorders:

The commonest side effects relate to gastrointestinal irritation (nausea, epigastric pain, constipation or diarrhoea). In the event of these ADRs, it may be helpful to reduce the dose or switch to an alternative iron salt.

Darkening of stools, black discoloration of the teeth and allergic reactions (due to metabisulphite in the syrup vehicle) may also occur.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms:
Ingestion of 20 mg/kg elemental iron is potentially toxic and 200-250 mg/kg is potentially fatal. No single method of assessment is entirely satisfactory - clinical

features as well as laboratory analysis must be taken into account. The serum iron taken at about 4 hours after ingestion is the best laboratory measure of severity.

Serum Iron	Severity
< 3 mg/L (55 micromol/L)	Mild toxicity
3-5 mg/L (55-90 micromol/L)	Moderate toxicity
> 5 mg/L (90 micromol/L)	Severe toxicity

Early signs and symptoms include nausea, vomiting, abdominal pain and diarrhoea. The vomit and stools may be grey or black.In mild cases early features improve but in more serious cases there may be evidence of hypoperfusion (cool peripheries and hypotension), metabolic acidosis and systemic toxicity. In serious cases there can be recurrence of vomiting and gastrointestinal bleeding, 12 hours after ingestion. Shock can result from hypovolaemia or direct cardiotoxicity. Evidence of hepatocellular necrosis appears at this stage with jaundice, bleeding, hypoglycaemia, encephalopathy and positive anion gap metabolic acidosis. Poor tissue perfusion may lead to renal failure. Rarely, gastric scarring causing stricture or pyloric stenosis (alone or in combination) may lead to partial or complete bowel obstruction 2-5 weeks after ingestion.

Management:

Supportive and symptomatic measures include ensuring a clear airway, monitor cardiac rhythm, BP and urine output, establishing IV access and administering sufficient fluids to ensure adequate hydration. Consider whole bowel irrigation. If metabolic acidosis persists despite correction of hypoxia and adequate fluid resuscitation, an initial dose of 50 mmol sodium bicarbonate may be given and repeated as necessary, for adults guided by arterial blood gas monitoring (aim for a pH of 7.4). Consider the use of desferrioxamine, if /the patient is symptomatic (other than nausea), serum iron concentration is between 3-5 mg/L (55-90 micromol/L) and still rising. Haemodialysis does not remove iron effectively but should be considered on a supportive basis for acute renal failure as this will facilitate removal of the iron-desferrioxamine complex.

PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Iron bivalent, oral preparations

ATC code: B03AA02

Iron is an essential constituent of the body, and is necessary for haemoglobin formation and the oxidative processes of living tissues. Iron and iron salts should be given for the treatment or prophylaxis of iron deficiency anaemias. Preparations of iron are administered by mouth, by intramuscular or intravenous injection.

Soluble ferrous salts are most effective by mouth. Ferrous fumarate is an easily absorbed source of iron for replacement therapy. It is a salt of ferrous iron with an organic acid and is less irritant to the gastro-intestinal tract than salts with inorganic acids.

5.2 Pharmacokinetic properties

Absorption

In the acid conditions of the gastric contents, ferrous fumarate is dissociated and ferrous ions are liberated. These ions are absorbed in the proximal portion of the duodenum.

The ferrous iron absorbed by the mucosal cells of the duodenum is oxidised to the ferric form, and this is bound to protein to form Ferritin.

Distribution

Ferritin in the mucosal cells releases iron into the blood, where it is bound to transferrin and passed into the iron stores - liver, spleen, and bone marrow.

These stores are a reserve of iron for synthesis of haemoglobin, myoglobin, and iron containing enzymes.

Elimination

Iron is lost from the body through loss of cells in urine, faeces, hair, skin, sputum, nails, and mucosal cells, and through blood loss.

Ferrous fumarate has the same pattern of absorption and excretion as dietary iron.

5.3 Preclinical safety data

No further data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Nipastat
Methylcellulose
Liquid glucose
Sucrose
Lecithin, Vegetable
Elderberry flavour
Sodium metabisulphite
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Protect from light. Store below 25°C.

6.5 Nature and contents of container

Amber glass bottle with polypropylene, child resistant, tamper evident closure with PET faced Aluminium foil/EPE wads.

Pack size: 1 x 200 ml

6.6 Special precautions for disposal

No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Mercury Pharmaceuticals Ltd,
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69 Old Broad Street,
London, EC2M 1QS, United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 12762/0223

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/12/1993

10 DATE OF REVISION OF THE TEXT

15/09/2023