SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fersaday 322mg Tablets

Ferrous Fumarate 322mg Film-Coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 322.0mg Ferrous Fumarate BP (equivalent to approximately 100 mg ferrous iron)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated Tablets

Each film coated tablet is brown ochre in colour and engraved ‘FE’ on one face and ‘322’ on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylaxis and treatment of iron deficiency states.

4.2 Posology and method of administration

Posology

Adults and the elderly: One tablet daily (the foil enclosing the tablet is printed with days of the week in sequence).

In severe or refractory iron deficiency, one tablet may be given twice a day.

Paediatric population: Ferrous Fumarate tablets are not intended for the treatment of children.

Method of administration:

Oral

4.3 Contraindications

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

Paroxysmal nocturnal haemoglobinuria, haemosiderosis, haemochromatosis, active peptic ulcer, repeated blood transfusions, regional enteritis, and ulcerative colitis. Ferasday tablets 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 needed when treating patients with iron deficiency anaemia in patients with treated or controlled peptic ulceration. Duration of treatment of uncomplicated iron deficiency anaemia should not usually exceed 6 months (or 3 months after reversal of the anaemia has been achieved).

Since anaemia due to combined iron and vitamin B12 or folate deficiencies may be microcytic in type, patients with microytic anaemia resistant to therapy with iron alone should be screened for vitamin B12 or folate deficiency.

Paediatric Population

Ferrous Fumarate tablets should be kept out of the sight and reach of children.

The label will state:

Important Warning: Contains Iron.
Keep out of the sight and reach 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.

This medicine contains less than 1 mmol sodium (23 mg) per dosage, that is to say essentially ‘sodium-free’.

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 Ferrous Fumarate

tablet 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 tablets can be used during pregnancy if clinically indicated.

Breast-feeding

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:

Rare (≥1/10 000 to <1/1 000):
Immune system disorders:
• Allergic reactions.

Not known: frequency cannot be estimated from the available data

Gastrointestinal disorders:

• Gastro-intestinal irritation and darkening of stools can occur with iron salts. Nausea and epigastric pain are dose-related but the relationship between dose and altered bowel habit (constipation or diarrhoea) is less clear. Oral iron, particularly modified-release preparations, can exacerbate diarrhoea in

patients with inflammatory bowel disease; care is also needed in patients with intestinal strictures and diverticular disease.

- Iron preparations taken orally can be constipating, particularly in older patients and occasionally lead to faecal impaction.

- If side-effects occur, the dose may be reduced; alternatively, another iron salt may be used but an improvement in tolerance may simply be a result of a lower content of elemental iron.

Paediatric population
Iron preparations are a common cause of accidental overdose in children

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 at: 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, monitoring of 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.

5 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

<u>Absorption</u>

Once in the stomach, the acid conditions of the gastric contents cause the dissociation of ferrous fumerate and ferrous ions are liberated. These ions are absorbed through 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 is passed onto the iron stores in the liver, spleen, and bone marrow.

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

Elimination

Iron is lost from the body through loss of cells i.e, urine, faeces, hair, skin, sputum, nails, sloughing of 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

Tablet Core

Maize Starch BP

Sodium Lauryl Sulfate BP

Gelatin BP

Paraffin Liquid BP

Film Coating

Acetylated Monoglyceride

Opadry20A270006

Opadry20A270006 contains:

Hypromellose

Iron Oxide Yellow
Titanium dioxide
Talc
Hydroxypropyl cellulose
Iron Oxide Red

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Protect from light.

Store below 25^0C.

6.5 Nature and contents of container

Cartons containing two blister packs of 14 tablets, prepared from White 250/60 micron PVC/PVDC film and printed 30 micron hard-tempered aluminium foil. 28 tablets in each carton or dispensing pack of 1000 tablets in Polypropylene container with tamper evident low density polyethylene cap.

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 Pharma Group Ltd

Dashwood House, 69 Old Broad Street,

London, EC2M 1QS, United Kingdom

8 MARKETING AUTHORISATION NUMBER

PL 10972/0041

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/01/2009

10 DATE OF REVISION OF THE TEXT

27/10/2025