SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Femarate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 200 mg of ferrous fumarate which equivalent to 65 mg of elemental iron.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylaxis and treatment of iron deficiency anemia.

4.2 Posology and method of administration

Posology

Adults and the elderly: Iron deficiency anemia - 1 tablet two to three times a day; prophylaxis - 1 tablet once or twice a day.

Paediatric population: Not recommended, suggest use of ferrous fumarate syrup.

The tablets are easy to swallow but may also be crushed or chewed being almost tasteless.

Rationale:

Taking into account the content of elemental iron and the referenced recommended daily dose of the same in deficiency states and for prophylaxis, the Femarate dosing is in need of revision.

Each Femarate tablet contains 200 mg ferrous fumarate which approximates to 65 mg of elemental iron- reference: (1) Goodman & Gilman's The pharmacological Basis of Therapeutics, 10th Edition, page no. 1499 (2) BNF

Recommended Doses:

1. (a) Iron Deficiency anemia: 100 to 200 mg elemental iron per day- [reference (1) BNF (2) G&G]. This equates to Femarate 1 tablet two or three times a day.
2. (b) Prophylaxis: Ferrous fumarate 200 mg once or twice a day (reference BNF) i.e. 60 to 120 mg elemental iron per day. This equates to Femarate 1 tablet once or twice daily.

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. Must not be used in anemias other than those due to iron deficiency.

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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 anemia who have treated or controlled peptic ulceration.

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

Because anemia due to combined iron and Vitamin B_{12} or folate deficiencies may be microcytic in type, patients with microcytic anemia resistant to treatment with iron alone should be screened for Vitamin B_{12} or folate deficiency.

Paediatric population

Should be kept out of the reach of children.

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 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.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

Not relevant.

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4.8 Undesirable effects

The following adverse reactions are classified by system organ class and ranked under heading of frequency using the following convention:
Common (≥1/100 to <1/10)
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 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 Health Product Vigilance Center; HPVC, Thai FDA

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 25 weeks after ingestion.

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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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-anemic preparations, iron preparations
ATC code: B03AA02
Iron is an essential constituent of the body, and is necessary for haemoglobin formation and for the oxidative processes of living tissues. Iron and iron salts should be given for the treatment or prophylaxis of iron deficiency anemias. 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.

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6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core tablet

Microcrystalline cellulose, Croscarmellose sodium, Sodium lauryl sulphate, Low-substituted hydroxypropyl cellulose, Colloidal silicon dioxide, Magnesium stearate.

Film-coating

Hypromellose, Talc, Sicovit red, Polyethylene glycol, Simethicone emulsion.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at temperature below 30º C, Protect from light.

6.5 Nature and contents of container

1. White HDPE bottle containing 1000 tablets per bottle.
2. Aluminium – amber PVC blister containing 10 tablets, 50 blisters per paper box.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

1A 539/46

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/12/2003

10 DATE OF REVISION OF THE TEXT

16/07/2024