SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

Pilferon 210/0.6mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sugar-coated tablet contains:

Ferrous Fumarate 210mg and

Folic Acid 0.6mg

Excipients with known effect:

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

Deep red, circular, biconvex sugar coated tablet plain on both sides.

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

Pediatric population:

Not recommended, suggest use of Fersamal syrup.

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

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 Fersamal dosing is in need of revision.

Each Fersamal tablet contains 210mg ferrous fumarate which approximates to 65-70mg of elemental iron- reference: (1) Goodman & Gilman's: The pharmacological Basis of Therapeutics, 10th Edition, page no. 1499 (2) BNF **Recommended Doses:**

(a) Iron Deficiency anaemia: 100 to 200mg elemental iron per day- [reference 1) BNF (2) G&G]. This equates to Fersamal 1 tablet two or three times a day.

(b) Prophylaxis: Ferrous sulphate 200mg once or twice a day (reference BNF) i.e. 60 to 120mg elemental iron per day. This equates to Fersamal 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 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 B_{12} or folate deficiencies may be microcytic in type, patients with microcytic anaemia resistant to treatment with iron alone should be screened for Vitamin B_{12} or folate deficiency.

This medicine contains less than 1 mmol sodium (23 mg) in each tablet that is to say essentially 'sodiumfree'.

Paediatric population

Fersamal should be kept out of the reach of children.

The label will state:

Important Warning:

Contains Iron.

Keep out of the 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.

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 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 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.

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 the Pharmacovigilance & Post-Marketing Surveillance for Phamatex Industries Limited at: https://forms.gle/VYSm47weo5k4FZ1g7 or check Phamatex Industries Limited Website for more details on Pharmacovigilance & Post-Marketing Surveillance.

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 irondesferrioxamine complex.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics 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 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 gastrointestinal 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 irons 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 a 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

Microcrystalline Cellulose

Sodium lauryl sulfate

Sodium Starch Glycolate

Magnesium Stearate

Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

No special precautions

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Aluminum foil (25 µm) and PVC film thickness of 250 µm blistered for 3 X 10 tablets in a secondary pack.

6.6 Special precautions for disposal <and other handling>

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. <APPLICANT/MANUFACTURER>

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