SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ferrous Fumarate 210 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 210 mg ferrous fumarate Ph. Eur., equivalent to 69 mg elemental iron.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Light brown, round, biconvex, uncoated tablet.

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

Adults and the elderly:

Iron deficiency anaemia: One tablet two to three times a day.

Prophylaxis: One tablet once or twice a day.

Paediatric population:

This product is not recommended in children.

Method of administration

For oral use.

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.
- Contraindicated 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.

Paediatric population

Ferrous Fumarate should be kept out of the 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 prominently on the front face of the packaging.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, 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, cefdinir, bisphosphonates, ciprofloxacin, entacapone, levodopa, levofloxacin, levothyroxine (thyroxine) (give at least 2 hours apart), moxifloxacin, mycophenolate mofetil, norfloxacin, ofloxacin, zinc, methyldopa, carbidopa and quinolone antibacterials. 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.

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 most common 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.

Very rare (<1/10,000):

Immune system disorders:

Rarely allergic reactions may 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 µmol/L)	Mild toxicity
3-5 mg/L (55-90 µmol/L)	Moderate toxicity
> 5 mg/L (90 µmol/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 µmol/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-anaemic 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 gastro-intestinal tract than salts with inorganic acids.

5.2 Pharmacokinetic properties

Absorption

In the acidic 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

Maize starch

Liquid paraffin

Gelatin

Sodium lauryl sulfate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

PVC/PVdC blisters with child-resistant paper laminate foil containing 28, 56, 84 or 112 tablets.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Kent Pharma UK Limited
2nd Floor
Connect 38
1 Dover Place
Ashford
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TN23 1FB

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PL 51463/0129

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