PRODUCT LITERATURE

FERROMAX TABLET 200MG

Each tablet contains
Ferrous Fumarate BP 200mg

Preservative
Sodium Benzoate BP 0.1%w/w

Product description
Round, brown coloured tablet

Pharmacodynamics and Pharmacokinetics
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.

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.
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.
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.

Indication
Prevention and treatment of iron-deficiency anaemia

Recommended dose
Adult: Usual dose range: Up to 600 mg daily. May increase up to 1.2 g daily if necessary.

Route of administration
Oral

Contraindications
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.

Warnings and Precautions
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.

Interactions with other medicaments
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**.**

Pregnancy and lactation
Pregnancy
Ferrous fumarate tablets can be used during pregnancy if clinically indicated.

Lactation
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.

Side effects
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

Symptoms and treatment of 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.

Storage Condition
Store below 30ºC, in a dry place, protected from direct light.
Keep out of reach from children

Shelf life
3 years from date of manufacture.

Packing
30's in HDPE Packing
100's in HDPE Packing

Name and Address of Manufacturer:
TERAPUTICS SDN. BHD.
(590500-W)
Lot 10 & 11, PERDA Industrial Park,
Lorong IKS Simpang Ampat B,
14100 Simpang Ampat, S.P.S.,

Pulau Pinang, Malaysia

Name and Address of Product Registration Holder/ Distributor:
ZONTRON PHARMACEUTICALS SDN.BHD. (445695-T)
Lot 10 & 11, PERDA Industrial Park,
Lorong IKS Simpang Ampat B,
14100 Simpang Ampat, S.P.S.,
Pulau Pinang, Malaysia

Malaysian Drug Registration No. MAL19940198XCZ

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