PACKAGE INSERT

FEROCOM TABLET

Each tablet contains:

Ferrous sulphate	180.0 mg
Nicotinamide	10.0 mg
Folic acid	5.0 mg
Thiamine HCl	3.0 mg
Riboflavine	1.5 mg

Product Description: Round, egg-yellow, sugar-coated tablets.

Indication:
It is indicated for the treatment of iron deficiency where there is an associated deficient intake or increased need for the relevant B vitamins. It is also indicated for the treatment of megaloblastic anemia caused by deficiency of folic acid.

Recommended Dosage:
For children 6 to 12 years of age: 1 tablet to be taken once daily.
For adults & elderly: 1 to 3 tablets a day in divided doses.

Route of Administration: Oral

Contraindications:
It is contraindicated in patients who have shown sensitivity to it.

Warnings and Precautions:
This product is not intended for treatment for pernicious anaemia or other megaloblastic anaemias where vitamin B12 is deficient.
It is also not intended for treatment of severe specific deficiency.
Care should be taken when given to patients with iron-storage or iron-absorption diseases, haemoglobinopathies, or existing gastro-intestinal disease.
The absorption of iron is inhibited or decreased in the presence of antacids containing carbonates, magnesium trisilicate or when taken with tea. Iron salts appear to reduce the effects of penicillamine. The absorption of iron salts and tetracyclines is diminished when they are taken concomitantly by mouth.

Interaction with Other Medicaments:
If treatment with both drugs is required, a time interval of about 2 to 3 hours should be allowed between each administration. The absorption of iron salts may also be decreased by some antacids. The response to iron may be delayed in patients receiving concomitant chloramphenicol therapy. Iron salts have been reported to decrease absorption and thus reduce the bioavailability and clinical effect of levodopa with carbidopa, methyldopa and penicillamine; decreased absorption and bioavailability has also been reported for the fluoroquinolones ciprofloxacin and ofloxacin when administrated with iron salts.

Pregnancy and Lactation: Not applicable.

Side Effects:
Allergic sensitization has been reported but rare.
Iron may cause gastro-intestinal discomfort, diarrhoea and vomiting. Large doses may have irritant or corrosive effects on the gastro-intestinal mucosa and necrosis and perforation may occur, stricture formation may subsequently follow. Symptoms include epigastric pain, diarrhoea, vomiting and haematemesis may occur. Circulatory failure may follow if the diarrhoea and haemorrhage are severe. Metabolic acidosis, convulsions and coma may occur. If the patient survives, symptoms of acute liver necrosis may develop and may lead to death due to hepatic coma.

Symptoms and Treatment of Overdose:
Adverse effects arising from overdosage of the B vitamins are remote.

Symptoms Arising from Overdosage of Iron:
Blood stained vomitus, hurried respiration, fast pulse rate, loose, dark and offensive stool. Circulatory failure after gastro-enteritis may cause death, but if immediate danger passes there may be delayed effects. After an interval of apparent recovery, colic and melaena may return. Drowsiness, stupor and restless convulsive movement may occur. If this dangerous phase is safely passed, hepatitis or nephropathy may be noted after 1- 2 weeks. Some months afterwards symptoms of pyloric stenosis may arise.

Treatment:
Emesis should be induced as soon as possible and a thorough gastric lavage performed preferably with 1 per cent solution of bicarbonate. A solution of 0.2 percent desferrioxamine should then be used and a portion left in the stomach. This compound is a peptide iron acceptor related to apoferritin. It should also be injected intramuscularly (2g 12 hourly for 2 days) and infused intravenously (not more than 80mg per kg in 24 hours). If necessary, repeat intramuscular injections of 2g of desferrioxamine every 12 hours.
Fluid loss should be replaced by the intravenous administration of compound sodium lactate injection or sodium chloride and dextrose injection.

Storage Conditions: Store at temperature 25°C. Protect from light.

Pack Size: A bottle of 60 and 90 tablets.
Pack Size (export only): A bottle of 1000 tablets.

Shelf-life: 3 years.

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN/LOCAL GENERAL PRACTITIONER/PHARMACIST.

Manufacturer & Product Registration Holder:
SUNWARD PHARMACEUTICAL SDN. BHD.
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