SCHEDULING STATUS: S1

PROPRIETARY NAME (AND DOSAGE FORM):

GULF FERROUS SULPHATE COMPOUND TABLETS

COMPOSITION:

Each tablet contains:

FeSO4 (dried)	170 mg
Manganese Sulphate	2, 5 mg
Copper Sulphate	2, 5 mg
Contains sugar:	(Dextrose monohydrate 20 mg and sucrose 9,132 mg)
Inactive ingredients:	Acacia, calcium carbonate, gelatine (bovine), kaolin, magnesium stearate, microcrystalline cellulose, talc, silicon dioxide, titanium dioxide

CATEGORY AND CLASS:

A 8.3 Erythropoietics (haematinics)

PHARMACOLOGICAL ACTION:

Iron is an essential constituent of the body, being necessary for haemoglobin formation and for the oxidative processes of living tissue. Ferrous Sulphate is one of the most widely used iron salts in the treatment of iron-deficiency anaemia.

INDICATIONS:

- Iron-deficiency anaemia.

CONTRA-INDICATIONS:

- Patients receiving repeated blood transfusions
- Anaemia is not produced by iron-deficiency unless iron-deficiency is also present.

WARNINGS AND SPECIAL PRECAUTIONS:

Care should be taken when **GULF FERROUS SULPHATE COMPOUND TABLETS** is given to patients with iron-storage or iron-absorption diseases, haemoglobinopathies, or existing gastro-intestinal disease.
GULF FERROUS SULPHATE COMPOUND TABLETS contain sucrose and dextrose which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take **GULF FERROUS SULPHATE COMPOUND TABLETS**.

INTERACTIONS:

GULF FERROUS SULPHATE COMPOUND TABLETS diminishes the absorption of tetracycline taken concomitantly by mouth. If treatment with both medicines is required, **GULF FERROUS SULPHATE COMPOUND TABLETS** should be administered three hours before or two hours after the tetracycline.
The absorption of iron is decreased in the presence of antacids or when taken with tea.

HUMAN REPRODUCTION:

GULF FERROUS SULPHATE COMPOUND TABLETS can safely be used before, during and after pregnancy as iron supplementation if necessary, and if recommended by a healthcare professional.
GULF FERROUS SULPHATE COMPOUND TABLETS is excreted through breast milk.

DOSAGE AND DIRECTIONS FOR USE:

Adults: The usual initial therapeutic dose is three to five tablets daily, in divided doses, followed by a maintenance dose of two tablets daily.
Children 6 to 12 years: Three tablets daily in divided doses.
Side effects can be reduced by taking tablets with or immediately after food.

SIDE EFFECTS:

Side effects include gastro-intestinal discomfort, diarrhoea and vomiting. Continued administration may cause constipation and faeces to become black in colour. This can be counteracted with a mild laxative if necessary.

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF ITS TREATMENT:

Symptoms of over-dosage include gastro-intestinal irritation and necrosis. Perforation may occur and stricture formation may subsequently follow.
Symptoms, which may not appear for several hours include epigastric pain, diarrhoea, vomiting and haematemesis. If haemorrhage and diarrhoea are severe, circulatory failure may follow, convulsions and coma may occur.
In treating iron poisoning, speed is essential to block absorption of iron from the alimentary tract. A dose of as little as 1 g should be considered toxic in children.
If desferrioxamine is not available, empty the stomach immediately by emesis and lavage using a 1 % to 5 % solution of sodium bicarbonate, and leave about 300 ml of the solution in the stomach. Fluid loss should be replaced by intravenous administration of Compound Sodium Lactate Injection or Sodium Chloride and Dextrose Injection. Exchange transfusion may be necessary in severe cases.
The following procedure has been recommended if desferrioxamine is available:
Intramuscularly inject 2 g desferrioxamine mesylate, dissolved in Water for Injection; wash out the stomach with a 1 % solution of sodium bicarbonate; give 5 g desferrioxamine mesylate, in 50 to 100 ml water, by mouth or by stomach tube; give desferrioxamine mesylate by intravenous infusion at a rate of not more than 15 mg per kilogram body mass per hour, maximum dosage 80 mg/kg in 24 hours; repeat intramuscular injections of 2 g desferrioxamine mesylate every 12 hours if necessary.

IDENTIFICATION:

A white to off-white, round, biconvex sugar-coated tablet plain on both sides.

PRESENTATION:

Patient ready packs (LDPE) of 28, 56 or 84 tablets.
Plastic containers (HDPE/PP) of 30, 100 or 500 tablets.

STORAGE INSTRUCTIONS:

Store at or below 25 °C. Protect from light and moisture. Keep the HDPE/PP containers tightly closed.
Do not remove tablets from patient ready packs or containers until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

H0825 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Gulf Drug Company (Pty) Ltd
22 Burnside Drive
Old Mill Industrial Park
Mount Edgecombe

DATE OF PUBLICATION OF PROFESSIONAL INFORMATION:

Date of the most recent amendment to the Professional Information: 09/09/2004
Date of registration: 1965