1 NAME OF THE MEDICINAL PRODUCT

Fesulf Tablets 200mg.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sugar coated tablet contains:
Dried Ferrous Sulphate B.P 200mg
equivalent to 65 mg ferrous iron.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Sugar Coated Tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Fesulf tablet is indicated in iron deficiency anaemia due to malabsorption of iron from the diet parasitic infestation. It is indicated in the prophylaxis of iron deficiency anaemia in pregnancy, breast feeding and after child birth.
It could also be used after excessive loss of blood due to accident orb post operation.

4.2 Posology and method of administration

Adults and children over 12years:
Iron Deficiency anaemia – one tablet 3times daily.
Prophylaxis – one tablet once daily.

Method of administration:
Oral Administration.

Tablets should be taken before meals or during meals, depending on gastrointestinaltolerance.

4.3 Contraindications

Fesulf should not be administered to patients with haemolytic anamia, peptic `ulcer, enteritis or ulcerative colitis and hypersensitivity to iron salts.

4.4 Special warnings and precautions for use

Fesulf should not be administered with antacids, tetracycline, and tea/coffee because absorption of iron is inhibited as a result of the formation of unabsorbable complexes with the constituents of these materials.

Administer with caution in patients with haemolytic anaemia, haemoglobinopathies, iron storage or iron absorption diseases, existing gastrointestinal disease.

Before starting treatment, it is important to exclude any underlying cause of the anaemia (e.g. gastric erosion, colonic carcinoma).
Due to the risk of mouth ulcerations and tooth discolouration, tablets should not be sucked, chewed or kept in the mouth, but swallowed whole with water.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration with tetracyclines may impair absorption of both agents. The absorption of ciprofloxacin, norfloxacin and ofloxacin and bisphosphonates is reduced by oral iron. Cholestyramine may bind iron to the gastrointestinal tract, thuspreventing its absorption. The absorption of iron salts is also decreased in the presence of antacids, preparations containing zinc, calcium, phosphorus, trientine, orwhen taken with tea, coffee, milk, eggs and whole grains. Iron supplements should not be taken within one hour before or two hours after ingestion of these products.
Iron salts may reduce the bioavailability of methyldopa. The absorption of levodopa and penicillamine may be reduced. Absorption of iron salts is enhanced by ascorbicacid and meat.
Dimercaprol: Avoid the concomitant use of iron with dimercaprol.

4.6 Pregnancy and lactation

Fesulf tablets are recommended for use in pregnancy and lactation, and nocontraindications to such are known.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Gastro-intestinal disturbances such as constipation, nausea, vomiting, stomach cramping.

Iron supplementation may cause the darkening of stool and staining of teeth.

4.9 Overdose

In the event of over dosage, the antidote is Gastric Lavage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Fesulf tablet is used in the treatment of iron deficiency anaemia.

Iron preparations have no intrinsic therapeutic activity except as a nutrient source: their use without evidence of iron deficiency, or reasonable expectation of its occurrence, is to be deprecated. Excessive iron is toxic and haemochromatosis can result from chronic injection of iron preparations used as tonics, especially in individuals with undiagnosed blood disorders. Patients with chronic anaemia are particularly at risk from iron storage disease.
Recently a severe iron overload myopathy has been described in patients given prophylactic iron indiscriminately while receiving haemodialysis. Genetic factors probably contribute to the risk of an iron storage disease.

It should be clear that although iron deficiency is easily treated, its detection does not constitute a complete diagnosis. Every effort should be made to determine why the patient has a state of negative iron balance. Attention should be given to hidden sources of haemorrhage (which may indicate serious urinary or gastrointestinal conditions) and also the possibility of malabsorption of iron caused by latent disease of the small intestine.

5.2 Pharmacokinetic properties

Iron is irregularly and incompletely absorbed from the gastrointestinal tract, the main sites of absorption being the duodenum and the jejunum. Absorption is aided by the acid secretion of the stomach or by dietary acids and is more readily affected when the iron is in the ferrous state or is part of the haem complex (haem-iron unit).
Absorption is also increased in conditions of iron deficiency or in the fasting state but decreased if the body stores are overloaded. Around 5-15% of the iron ingested in food is absorbed. **Following absorption,** the majority of iron is bound to transferrin and transported to the bone marrow where it is incorporated into haemoglobin. The remainder is stored within ferritin or haemosiderin or is incorporated into myoglobin with smaller amounts occurring in haem-containing enzymes or in plasma bound to transferrin. Only very small amounts are excreted as the body reabsorbs the iron after the haemoglobin has broken down.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Starch
Methyl paraben
Propyl paraben
Talcum powder
Magnesium stearate
Aerosil

Coating:
Sugar
Talcum Powder
Calcium Carbonate
Gelatin
Shellac Flakes
Ethanol
Titanium dioxide
Colour Ponceau 4red
Carnuba wax.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Keep in a dry place at a temperature below 30° C away from light.

Keep all medicines out of reach of children.Nature and contents of container

Fesulf tablets are presented in plastic cup and cover for Pack sizes of x100 and x1000 and Blisters for pack sizes of 10 x 10 and 2 x 50 and packed in a carton.

6.5 Special precautions for disposal

No special requirement.

7 APPLICANT/MANUFACTURER

Therapeutic Laboratories Nig. Ltd.
372, Ikorodu, Road, Maryland, Lagos.
08037266866
Regulatory.therapeutic@gmail.com