SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT.

Ferrous Sulphate Tablets.

Strength:

Dried Ferrous Sulphate 200mg.

Pharmaceutical Form:

Film Coated Tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION.

Each film coated tablet contains**:** Dried Ferrous Sulphate BP 200mg.

Excipient with known effect:

Sodium

Full list of excipients is provided in section 6.1

3. PHARMACEUTICAL FORM.

Film Coated Tablets.

Maroon, circular, biconvex film coated tablets plain on both sides. Packed in PVC/ALU blisters of 10 x 10's, 100 x 10's in a unit box, 1000s in HDPE container with literature insert.

4. CLINICAL PARTICULARS.

4.1 Therapeutic indications:

Ferrous Sulphate tablets are indicated for prevention and treatment of iron-deficiency anaemias.

4.2 Posology and method of administration:

Each 200mg Ferrous Sulfate Tablet is equivalent to 65mg of ferrous iron:

Adults	**Treatment:** 2-3 tablets daily in divided doses. **Prophylaxis:** One tablet daily.
Elderly	The usual adult dose can be administered.
Children 6-12yrs	**Treatment:** Children weighing over 22kg- one tablet daily. Children weighing over 44kg - one tablet twice daily. Children weighing over 66kg - one tablet three times daily.

Method of Administration: For oral administration.

The tablets should not be sucked, chewed or kept in the mouth, but swallowed whole with water. Tablets should be taken before meals or during meals, depending on gastrointestinal tolerance.

4.3 Contraindications:

Hypersensitivity to the active substance; patients receiving repeated blood transfusions; concomitant parenteral iron; hemochromatosis and other iron overload syndromes.

4.4 Special warnings and special precautions for use:

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

Patients with rare hereditary problems of galactose intolerance or fructose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Due to the risk of mouth ulcerations and tooth discoloration, 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 is reduced by oral iron.

Cholestyramine my bind iron to the gastrointestinal tract, thus preventing its absorption.

The absorption of iron salts is also decreased in the presence of antacids, preparations containing zinc, calcium, phosphorus, or when tea, coffee, milk, eggs and whole grains. Iron supplements should not be taken within one hour before 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 ascorbic acid and meat.

4.6 Pregnancy and lactation:

Use of any drug during the first trimester of pregnancy should be avoided if possible. Thus administration of iron during the first trimester requires definite evidence of iron deficiency. Prophylaxis of iron deficiency during the remainder of pregnancy is justified.

4.7 Effects on ability to drive and use machines:

None Known.

4.8 Undesirable effects:

Although iron preparations are best absorbed on an empty stomach, they may be taken after food to reduce gastrointestinal side-effects; they may disclour (blacken) stool.
Nausea and epigastric pain are dose related but the relationship between dose and altered bowel habit (constipation, diarrhoea) is less clear.
Iron preparations taken orally may have a constipating effect, particularly in older patients, occasionally leading to faecal impaction.

Reporting of adverse reactions:

Reporting suspected adverse reactions after authorization 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 provided channels.

4.9 Overdose:

Acute iron overdosage can be divided into four stages. In the first phase, which occurs up to 6 hours after oral
ingestion, gastrointestinal toxicity, notably vomiting and diarrhoea, predominates. Other effects may include cardiovascular disorders such as hypotension and tachycardia, metabolic changes including acidosis and hyperglycaemia, and CNS depression ranging from lethargy to coma.
Patients with only mild to moderate poisoning do not generally pass this first phase.
The second phase may occur at 6-24 hours after ingestion and is characterised by a temporary remission or clinical stabilisation.
In the third phase gastrointestinal toxicity recurs together with shock, metabolic acidosis, convulsions, coma, hepatic necrosis and jaundice, hypoglycaemia, coagulation disorders, oliguria or renal failure, and pulmonary oedema.
The fourth phase may occur several weeks after ingestion and is characterised by gastrointestinal obstruction and possibly late hepatic damage.
Overdosage of ferrous salts is particularly dangerous to young children.
Treatment consists of gastric lavage followed by the introduction of 5g desferrioxamine into the stomach. Serum iron levels should be monitored and in severe cases iv desferrioxamine should be given together with supportive and symptomatic measures as required.
Gastric lavage with 5% sodium bicarbonate and saline cathartics (e.g., sodium sulfate 30g for adults); milk and eggs with 5g bismuth carbonate every hour as demulcents.
Blood or plasma transfusion for shock, oxygen for respiratory embarrassment.
Chelating agents (e.g., disodium calcium edetate) ma tried (500mg/500ml by continuous iv infusion). Dimercaprol should not be used since it forms a toxic complex wit iron. Desferrioxamine is a specific iron chelating agent and severe acute poisoning in infants should always be treated with desferrioxamine at a dose of 90mg/kg IM

followed by 15mg/kg per hour IV until the serum iron is within the plasma binding capacity.

5. PHARMACOLOGICAL PROPERTIES.

5.1 Pharmacodynamic properties:

Pharmacotherapeutic Group: Iron bivalent, oral preparations.

ATC Code: B03AA07.

Ferrous sulfate is used in the treatment of iron deficiency anaemias.

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. Iron, in excess, is toxic and haemochromatosis may 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 iron overload.

It should be clear that although iron deficiency is readily treated, its detection does not constitute a complete diagnosis. Every effort should be made to determine why the patient has entered 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 intestines.

5.2 Pharmacokinetic properties:

Iron is irregularly and incompletely absorbed from the gastrointestinal tract, the main sites of absorption being the duodenum and 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) Absorption is also increased in conditions of iron deficiency or in the fasting state but is decreased if the body stores are overloaded. Only about 5-15% of the iron ingested in food is normally absorbed.

5.3 Preclinical safety data:

Not Applicable.

6. PHARMACEUTICAL PARTICULARS.

6.1 List of excipients:

- Dextrose Anhydrous
- Crospovidone
- Microcrystalline Cellulose pH 101

- Sodium Starch Glycolate
- Sodium Lauryl Sulfate
- Purified Talc
- Magnesium Stearate
- Tab coat TC Maroon
- Purified Water

6.2 Incompatibilities:

None known.

6.3 Shelf life:

36 Months from the manufacture date.

6.4 Special precautions for storage:

Store in a dry place, below 30°C.

Protect from light.

Keep all medicines out of reach of children.

6.5 Nature and contents of container:

Maroon, circular, biconvex film coated tablets plain on both sides. Packed in PVC/ALU blisters of 10 x 10's, 100 x 10's in a unit box, 1000s in HDPE container with literature insert.

6.6 Special precautions for disposal and other handling:

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6.7 Distribution Category:

Prescription Only Medicine (POM).

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES.

Marketing Authorization holder:

Company Name: Laboratory and Allied Limited.

Address: Plot No. 209/10349, Opposite Sameer Business Park, next to Libra House, Mombasa Road, P.O. Box 42875 GPO 00100, Nairobi-Kenya.

Country: Kenya

Telephone: +254 20 8040306

Telefax: +254 20 8040309

E-Mail: info@laballied.com.

Manufacturing Site Address:

Company Name: Laboratory and Allied Limited.

Address: Plot No. 209/10349, Opposite Sameer Business Park, next to Libra House, Mombasa Road, P.O. Box 42875 GPO 00100, Nairobi-Kenya.

Country: Kenya

Telephone: +254 20 8040306.

Telefax: +254 20 8040309.

E-Mail: info@laballied.com

8. MARKETING AUTHORIZATION NUMBER

Kenya: Registration No.: H90418.

9. DATE OF FIRST <REGISTRATION> / RENEWAL OF THE <REGISTRATION>

Date of first authorization: 16/03/1990.

Date of latest renewal: 09/08/2026

10. DATE OF REVISION OF THE TEXT

August, 2026