1. Name of the Medicinal Product

1.1 (Invented) Name Of The Medicinal Product

FERROLAB-12

1.2 Strength

Each hard gelatin capsule contains:

Ferrous Fumarate	BP	200mg
Vitamin B_{12}	BP	100mcg
Folic Acid	B.P	1000mcg

1.3. Pharmaceutical Dosage Form

Solid Dosage Form (Capsule)

2. Qualitative And Quantitative Composition

Each hard gelatin capsule contains:

Ferrous Fumarate	BP	200mg
Vitamin B_{12}	BP	100mcg
Folic Acid	B.P	1000mcg
Excipients		q.s.

Approved colour used in empty gelatin capsule shells.

3. Pharmaceutical Form

Capsules for Oral Use Only

4. Clinical Particulars

4.1 Therapeutic Indications

Ferrolab-12 is a haematinic containing added vitamins. It is recommended for prophylaxis of iron and folic acid deficiency during pregnancy.Ferrolab-12 is indicated for the treatment and maintenance of common anaemias, including iron-deficient anaemias, megaloblastic anaemias of pregnancy, pellagra and those of nutritional origin. All of the other means that are recognised as suited to the treatment of these anaemias should also be employed.

4.2 Posology and Method of Administration

Adults and the Elderly

Iron deficiency anaemia - 1 capsule two to three times a day; prophylaxis - 1 capsule once or twice a day.

Children:

Not recommended.

Method of administration:

Oral **Or As directed by the Physician.**

4.3 Contraindications

Contra-indicated in patients with megaloblastic anaemia due to vitamin B12 deficiency and in patients with a known hypersensitivity to the product or its ingredients. Not intended for the prevention or treatment of anaemia in men, non-pregnant women or children. Use in patients with haemosiderosis, haemochromatosis and haemoglobinopathies.

Use in patients anaemias other than those due to iron deficiency.

Use in patients with inflammatory bowel disease, including regional enteritis and ulcerative colitis, intestinal strictures and diverticulae.

Concomitant use with parenteral iron.

Use in patients with active peptic ulcer.

Use in patients who require repeated blood transfusion.

Haemoglobinopathies

Concomitant use with parenteral iron

Concomitant use with dimercaprol

4.4 Special Warning and Precautions For Use

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.

Keep out of the reach and sight of children, as overdose may be fatal.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Ferrous Fumarate

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 Fersamal is given with tetracycline. Absorption of oral iron is reduced by calcium salts, Magnesium salts (as magnesium trisilicate), Trientine.

Vitamin B12

Absorption may be reduced by Para-aminosalicylic acid, colchinine, biguanides, neomycin, cholestyramine, potassium chloride, methyldopa, and cimetidine.

Patients treated with chloramphenicol may respond poorly to this medicine

Serum levels of this medicine may be lowered by oral contraceptives. These interactions are unlikely to have clinical significance. Anti-metabolities and most antibiotics invalidate vitamins B12 assays by microbiological techniques.

Folic Acid

Absorption of folic acid may be reduced by sulfasalazine.

Concurrent administration with cholestyramine may interfere with folic acid absorption. Patients on prolonged cholestyramine therapy should take folic acid 1 hour before or 4 to 6 hours after receiving cholestyramine.

Antibiotics may interfere with the microbiological assay for serum and erythrocyte folic acid concentrations and may cause falsely low results.

Trimethoprim or sulfonamides, alone or in combination as co-trimoxazole, may reduce the effect of folic acid and this may be serious in patients with megaloblastic anaemia.

Serum levels of anticonvulsant drugs (phenytoin, phenobarbital, primidone) may be reduced by administration of folate and therefore patients should be carefully monitored by the physician and the anticonvulsant drug dose adjusted as necessary.

Fluorouracil toxicity may occur in patients taking folic acid and this combination should be avoided.

Edible clay or antacids containing aluminium or magnesium may reduce folic acid absorption. Patients should be advised to take antacids at least two hours after administration of folic acid.

Folic acid may reduce intestinal absorption of zinc (of particular importance in pregnancy).

4.6 Pregnancy and Lactation

Ferrolab 12 capsules is suitable for use during pregnancy & Lactation.

4.7 Effects on Ability to Drive and Use Machines

Not Applicable.

4.8 Undesirable Effects

Side effects may include nausea, vomiting, diarrhoea, constipation and other gastro-intestinal disturbances. Side effects may be minimised by taking the product with or after food or by starting with a small dose and increasing gradually.

Haemosiderosis may occur as a result of excessive or mistaken therapy.

Rarely, folic acid may cause allergic reactions and gastrointestinal disturbances.

Circulatory failure may follow if the diarrhoea and haemorrhage are severe. Hours or days later, after apparent recovery, 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.

4.9 Overdose

Initial symptoms of iron overdosage include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycemia and metabolic acidosis may occur. However, if overdosage is suspected, treatment should be implemented immediately. In severe cases, after a latent phase, relapse may occur after 24-48 hours manifested by hypotension, coma, hypothermia, hepatocellular necrosis, renal failure, pulmonary oedema, diffuse vascular congestion, coagulopathy and/or convulsions. In many cases, full recovery may be complicated by long-term effects such as hepatic necrosis, toxic encephalitis, CNS damage and pyloric stenosis.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Ferrous Fumarate

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.

Vitamin B12

This medicine contain cyanocobalamin vitamin B 12, which is used for the treatment of pernicious anaemia, and nutritional deficiencies of vitamin B 12 which results in macrocytic anaemia.

Folic Acid

The mucosa of the duodenum and upper part of the jejunum are rich in dihydrofolate reductase, where folates and folic acid are absorbed. Once absorbed, folic acid is rapidly reduced and then methylated to form tetrahydrofolic acid derivatives which are rapidly transported to the tissues.

5.2 Pharmacokinetic Properties

Ferrous Fumarate

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.

Vitamin B12

The absorption of cobalamins from the gut is dependent upon the glycoprotein intrinsic factor. Cobalamins are transported rapidly into the blood bound to protein, known as transcobalamins. Cobalamins are stored in the liver and excreted in the bile. They are known to cross the placenta.

Folic Acid

Folic acid is readily absorbed following oral dosage, and is extensively bound to plasma proteins.

5.3 Preclinical Safety Data

This product has been available for many years and its side effects and clinical profile are well-understood, therefore no further data is provided.

6. Pharmaceutical Particulars

6.1 List of Excipients

Maize Starch BP

Lactose BP

Sodium Benzoate BP

Thio urea BP

Hydrophobic Colloidal Anhydrous Silica BP

6.2 Incompatibilities

All the Active ingredients and excipients was compatible.

6.3 Shelf Life

<36 Months>

6.4 Special Precautions for Storage

Store in a cool (below25°C), dry and dark place.

Keep all medicines out of reach of children.

6.5 Nature and Contents of Container

2x15 Capsules in Alu-PVC Blister in a unit carton along with pack insert.

6.6 Special Precautions for Disposal and Other Handling

No special precautions for disposal and other handling.

7. Registrant/Sole Agent

EMBASSY PHARMACEUTICAL & CHEMICAL LTD.

41, Ademola Street, South West Ikoyi,

Lagos, Nigeria. Tel.: 01-2900791

8. Manufacturer

LABORATE PHARMACEUTICALS INDIA LIMITED

51, Indl. Area, Gondpur, Paonta sahib, H.P. (INDIA)

HO: E-11, Industrial Area, Panipat – 132103.

9. Date of Revision of Text

To be given after approval of product

10. Dosimetry (If applicable)

Not applicable

11. Instructions for Preparation of Radiopharmaceuticals (If applicable)

Not applicable