1. Name of the Medicinal Product

1.1 Name of the Medicinal Product

FERROLAB

(Iron Sucrose Injection USP)

1.2. Strength

100mg/5mL

1.3. Pharmaceutical Dosage Form

Parenteral Preparation (Sterile) – Liquid Injection

Qualitative and Quantitative Composition

Qualitative Declaration

The **FERROLAB** contains Iron Sucrose USP

Quantitative Declaration

Each 5ml contains:

Ferric Hydroxide in complex with Sucrose

Eq. to Elemental Iron 100mg

Water for Injections BP q.s.

3. Pharmaceutical Form

Parenteral Preparation (Sterile) – Liquid Injection

4. Clinical Particulars

4.1 Therapeutic Indications

Ferrolab is indicated for the treatment of iron deficiency in the following indications:

• Where there is a clinical need for a rapid iron supply,

• In patients who cannot tolerate oral iron therapy or who are non-compliant,

• In active inflammatory bowel disease where oral iron preparations are ineffective,

• In chronic kidney disease when oral iron preparations are less effective.

The diagnosis of iron deficiency must be based on appropriate laboratory tests (e.g. Hb, serum ferritin, TSAT, serum iron, etc.). (Hb haemoglobin, TSAT transferrin saturation)

4.2 Posology and Method of Administration

Adults

5 - 10 ml of Ferrolab (100 - 200 mg iron) 1 to 3 times a week.

Paediatric population

Not recommended for use in children.

Method of administration

Ferrolab must only be administered by the intravenous route. This may be by a slow intravenous injection, by an intravenous drip infusion or directly into the venous line of the dialysis machine.

Intravenous drip infusion

Ferrolab must only be diluted in sterile 0.9% m/V sodium chloride (NaCl) solution. Dilution must take place immediately prior to infusion and the solution should be administered as follows:

Ferrolab dose (mg of iron)	Ferrolab dose (ml of ferrolab)	Maximum dilution volume of sterile 0.9% m/V NaCl solution	Minimum Infusion Time
50 mg	2.5 ml	50 ml	8 minutes
100 mg	5ml	100ml	15 minutes
200mg	10ml	200ml	30 minutes

For stability reasons, dilutions to lower Ferrolab concentrations are not permissible.

Method of administration

For I.V. Use Only

4.3 Contraindications

The use of Ferrolab is contraindicated in the following conditions:

Hypersensitivity to the active substance, to Ferrolab or any of its excipients.

Known serious hypersensitivity to other parenteral iron products.

Anaemia not caused by iron deficiency

Evidence of iron overload or hereditary disturbances in utilisation of iron.

4.4 Special Warning and Precautions for Use

Parenterally administered iron preparations can cause hypersensitivity reactions including serious and potentially fatal anaphylactic/anaphylactoid reactions. The risk of hypersensitivity reactions is enhanced for patients with known allergies including drug allergies, including patients with a history of severe asthma, eczema or other atopic allergy.

Facilities for cardio respiratory resuscitation and equipment for handling acute anaphylactic/anaphylactoid reactions should be available, including an injectable 1:1000 adrenaline solution. Additional treatment with antihistamines and/or corticosteroids should be given as appropriate.

In patients with liver dysfunction, parenteral iron should only be administered after careful risk/benefit assessment. Parenteral iron administration should be avoided in patients with hepatic dysfunction where iron overload is a precipitating factor, in particular Porphyria Cutanea Tarda (PCT). Careful monitoring of iron status is recommended to avoid iron overload.

Parenteral iron should be used with caution in the case of acute or chronic infection. It is recommended that the administration of Ferrolab is stopped in patients with bacteraemia. In patients with chronic infection, a risk/benefit evaluation should be performed.

Paravenous leakage must be avoided because leakage of ferrolab at the injection site can lead to pain, inflammation and brown discoloration of the skin.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

As with all parenteral iron preparations, Ferrolab should not be administered concomitantly with oral iron preparations since the absorption of oral iron is reduced. Therefore, oral iron therapy should be started at least 5 days after the last injection of Ferrolab.

4.6 Pregnancy and Lactation

Used with caution

4.7 Effects on Ability to Drive and Use Machines

Not reported

4.8 Undesirable Effects

Anaphylactoid/anaphylactic reactions, angioedema, Depressed level of consciousness, confusional state, loss of consciousness, anxiety, tremor, Urticaria, erythema.

4.9 Overdose

Overdose can cause iron overload which may manifest itself as haemosiderosis. Overdose should be treated, as deemed necessary by the treating physician, with an iron chelating agent or according to standard medical practice.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Anti-anaemic preparation

ATC code: B03AC

Mechanism of action:

Ferrolab, is composed of a polynuclear iron(III)-hydroxide core surrounded by a large number of non-covalently bound sucrose molecules. The complex has a weight average molecular weight (Mw) of approximately 43 kDa. The polynuclear iron core has a structure similar to that of the core of the physiological iron storage protein ferritin. Following intravenous administration, the polynuclear iron core from the complex is taken up predominantly by the reticuloendothelial system in the liver, spleen, and bone marrow. In a second step, the iron is used for the synthesis of Hb, myoglobin and other iron-containing enzymes, or stored primarily in the liver in the form of ferritin.

Pharmacokinetic

5.2 Pharmacokinetic Properties

Distribution

In the first 6–8 hours, was taken up by the liver, spleen and bone marrow. The radioactive uptake by the macrophage-rich spleen is considered to be representative of the reticuloendothelial iron uptake.

Following intravenous injection of a single 100mg iron dose of iron sucrose in healthy volunteers, maximum total serum iron concentrations were attained 10 minutes after injection and had an average concentration of 538 µmol/l. The volume of distribution of the central compartment corresponded well to the volume of plasma (approximately 3 litres).

Biotransformation

Upon injection, sucrose largely dissociates and the polynuclear iron core is mainly taken up by the reticuloendothelial system of the liver, spleen, and bone marrow. At 4 weeks after administration, red cell iron utilization ranged from 59 to 97%.

Elimination

Renal elimination of iron, occurring in the first 4 hours after injection of a Ferrolab dose of 100mg iron, corresponded to less than 5% of the dose. After 24 hours, the total serum iron concentration was reduced to the pre-dose level. Renal elimination of sucrose was about 75% of the administered dose.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity, genotoxicity and toxicity to reproduction and development.

6.0 Pharmaceutical Particulars

6.1 List of excipients

Sodium Chloride BP

Hydrochloric acid BP

Water for injections BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

<24 Months>

6.4 Special Precautions for Storage

Do not store above 30°C. Do not freeze.

Keep out of reach of children.

6.5 Nature and Contents of Container

5x5 ml ampoules packed in a unit carton along with pack insert.

6.6 Special Precautions for Disposal and Other Handling

No special requirements.

7.0 Registrant/Sole Agent

EMBASSY PHARMACEUTICAL & CHEMICAL LTD.

41, Ademola Street, South West Ikoyi,

Lagos, Nigeria.Tel.: 01-2900791

8. Manufacturer

LABORATE PHARMACEUTICALS INDIA LIMITED

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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