REDULID HB

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.
Abbreviated Prescribing information for REDULID HB (Iron (Emulsified Ferric Pyrophosphate), Folic Acid and Glycine Capsule**)**

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: The polynuclear iron core has a structure similar to that of the core of the physiological iron storage protein ferritin. The complex is designed to provide, in a controlled manner, utilisable iron for the iron transport and storage proteins in the body (i.e., transferrin and ferritin, respectively).Following 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.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: Iron: Hypersensitivity to the active substance, to Iron 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. **Folic Acid:** Contra-indicated in patients with megaloblastic anaemia due to vitamin B_{12} 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. **Glycine:** Amino acid metabolism disorders, severe hyperglycaemia, metabolic acidosis, hyperlactataemia, It containing electrolytes should not be used in patients with hyperkalaemia, hypernatraemia and in patients with pathologically elevated plasma concentrations of magnesium, calcium and/or phosphorus.

WARNINGS & PRECAUTIONS: Iron: 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. There is also an increased risk of hypersensitivity reactions to parenteral iron complexes in patients with immune or inflammatory conditions, each patient should be observed for adverse effects for at least 30 minutes following each Iron injection. 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. **Folic Acid:** The dose of FA provided is inadequate for the treatment of megaloblastic anaemias, with Iron preparations, black colour of the faeces observed, which may interfere with tests used for detection of occult blood in the stools.The label will state: “Important warning: Contains iron. Keep out of reach and sight of children, as overdose may be fatal”. **Glycine:** Warnings: Hypersensitivity/infusion reactions including hypotension, hypertension, peripheral cyanosis, tachycardia, dyspnoea, vomiting, nausea, urticaria, rash, pruritus, erythema, hyperhidrosis, pyrexia, and chills have been reported with formulations. Special clinical monitoring is required at the beginning of any intravenous

infusion, if signs of pulmonary distress occur, the infusion should be stopped and medical evaluation initiated. Precautions: Severe water and electrolyte equilibration disorders, severe fluid overload states, and severe metabolic disorders should be corrected before starting the infusion, Metabolic complications may occur if the nutrient intake is not adapted to the patient's requirements, or the metabolic capacity of any given dietary component is not accurately assessed.

DRUG INTERACTION: Iron: As with all parenteral iron preparations, it should not be administered concomitantly, therefore, oral iron therapy should be started at least 5 days after the last injection of it. **Folic Acid:** Iron chelates with concomitantly administered tetracyclines, and absorption of both agents may be impaired, allow an interval of 2-3 hours if treatment with both drugs is necessary. Absorption of iron may be reduced in the presence of antacids and proton pump inhibitors which reduce stomach acid. Iron absorption may also be reduced in the presence of food (e.g. tea, coffee, wholegrain cereals, eggs and milk), neomycin and cholestyramine. Bicarbonates, carbonates, oxalates, or phosphates, may impair the absorption of iron by the formation of insoluble complexes. Iron absorption may be increased by ascorbic or citric acid. The hypotensive effect of methyldopa is reduced by iron.Concomitant use of iron and dimercaprol should be avoided as toxic complexes may form. **Glycine:** No interaction studies have been performed.

ADVERSE REACTIONS: Iron: Hypersensitivity, Anaphylactoid/anaphylactic reactions, angioedema, Dysgeusia, Headache, dizziness, paraesthesia, hypoaesthesia, Syncope, somnolence, Depressed level of consciousness, confusional state, loss of consciousness, anxiety, tremor, Palpitations, Bradycardia, tachycardia, Kounis syndrome, Hypotension, hypertension, Flushing, phlebitis, Circulatory collapse, thrombophlebitis, Dyspnoea, Bronchospasm, Chromaturia, Nausea, Vomiting, abdominal pain, diarrhoea, constipation, Pruritus, rash, Urticaria, erythema, Muscle spasm, myalgia, arthralgia, pain in extremity, back pain, Chills, asthenia, fatigue, oedema peripheral, pain, Chest pain, hyperdrosis, pyrexia, Cold, sweat, malaise, pallor, influenza like illness. **Folic Acid**: Nausea, vomiting, constipation, diarrhoea, Allergic reactions, anaphylactic reaction, Haemosiderosis. **Glycine**: Hypersensitivity, Hypotension, Hypertension, Peripheral cyanosis, Tachycardia, Dyspnoea, Vomiting, Nausea, Urticaria, Rash, Pruritus, Erythema, Hyperhidrosis, Pyrexia, Chills, Anaphylaxis, Pulmonary vascular precipitates, Hyperglycaemia, Hyperammonemia, Azotemia, Hepatic failure, Hepatic cirrhosis, Hepatic fibrosis, Cholestasis, Hepatic steatosis, Blood bilirubin increased, Hepatic enzyme increased, Cholecystitis, Cholelithiasis, Infusion site thrombophlebitis, Venous irritation, hyperglycaemia, glycosuria, and hyperosmolar syndrome may occur.

Manufactured by:

Tirupati Lifesciences Private Limited.
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(Additional information is available on request)