NEW REDULID HB

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for NEW REDULID HB [Iron (Ferric Pyrophosphate) With Vitamin C, Vitamin B12, Folic Acid, Glycine Tablet]

[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.

INDICATIONS: The prophylaxis of iron and folic acid deficiencies during pregnancy. Parenteral nutrition when oral or enteral alimentation is impossible, insufficient, or contraindicated. For patient undergoing long-term parenteral nutrition, the addition of a lipid emulsion to NEW REDULID HB in order to supply both calories and essential fatty acids is possible. NEW REDULID HB is also 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 and in chronic kidney disease when oral iron preparations are less effective.

DOSAGE AND ADMINISTRATION: Swallow intact tablet with water. Recommended Usage Level: 1 Tablet daily. The product is not to be used by children under 5 years, adolescents, and elderly, except when medically advised by a physician or certified dietician or nutritional professional. This product to be taken by Pregnant, Nursing, and lactating women under medical advice of physician or certified dietician or nutritional professional. NOT FOR PARENTERAL USE.

CONTRAINDICATION: ***Iron*****:** Hypersensitivity to the active substance, to it or any of its excipients, known serious hypersensitivity to other parenteral iron products, anemia 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 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, and use in patients who require repeated blood transfusion. ***Glycine*****:** Known hypersensitivity to any of the active substances or excipients listed or to the components of the container, 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, as for other calcium-containing infusion solutions, concomitant treatment with ceftriaxone and it is contraindicated in newborns (≤28 days of age), even if separate infusion lines are used (risk of fatal ceftriaxone calcium salt precipitation in the neonate's bloodstream), regarding co-administration in older patients.

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 INTERACTIONS: ***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*****:** Vomiting, Haemosiderosis. ***Glycine*****:** Peripheral cyanosis, Tachycardia, Dyspnoea, 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.

MARKETED BY:

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(Additional information is available on request)