REDULID FCM

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

Abbreviated Prescribing information for **REDULID FCM** (Ferric Carboxymaltose Injection (100 mg/2 ml)(500 mg/10 ml)(750 mg/15 ml)(1000 mg/20 ml)) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Ferric carboxymaltose is a colloidal iron (III) hydroxide in complex with carboxymaltose, a carbohydrate polymer that releases iron.

INDICATIONS: REDULID FCM is indicated for the treatment of iron deficiency in adults when oral iron preparation are ineffective or cannot be used.

DOSAGE AND ADMINISTRATION: As prescribed by the physician.

CONTRAINDICATION: Contraindicated in cases of known hypersensitivity to Ferric Carboxymaltose Injection or to any of its excipients, known serious hypersensitivity to other parenteral iron products, anaemia not attributed to iron deficiency, e.g. other microcytic anaemia, evidence of iron overload or disturbances in utilization of iron and in pregnancy in the first trimester.

WARNINGS & PRECAUTIONS: Parenterally administered iron preparations can cause hypersensitivity reactions including anaphylactoid reactions,which may be potentially fatal. Therefore, facilities for cardio-pulmonary resuscitation must be available. Hypersensitivity reactions have also been reported after previously uneventful doses of parenteral iron complexes. The risk is enhanced for patients with known allergies including drug allergies, including patients with a history of severe asthma, eczema or other atopic allergy. There is also an increased risk of hypersensitivity reactions to parenteral iron complexes in patients with immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis). Ferric Carboxymaltose Injection should only be administered when staff trained to evaluate and manage anaphylactic reactions is immediately available, in an environment where full resuscitation facilities can be assured. Each patient should be observed for adverse effects for at least 30 minutes following each Ferric Carboxymaltose Injection. If hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be stopped immediately. 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 iş a precipitating factor, in particular Porphyria Cutanea Tarda (PCT). Careful monitoring of iron status is recommended to avoid iron overload. No safety data on haemodialysis-dependent chronic kidney disease patients receiving single doses of more than 200 mg iron are available. Parenteral iron must be used with caution in cases of acute or chronic infection, asthma, eczema or atopic allergies. It is recommended that the administration of Ferric Carboxymaltose Injection is stopped in patients with ongoing bacteremia. In patients with chronic infection a risk/benefit evaluation has to be performed, taking into account the suppression of erythropoiesis. Caution should be exercised to avoid paravenous leakage when administering Ferric Carboxymaltose Injection. Paravenous leakage of Ferric Carboxymaltose Injection at the injection site may lead to brown discolouration and irritation of the skin. In case of paravenous leakage, the administration of Ferric Carboxymaltose Injection must be stopped immediately. The use of Ferric Carboxymaltose Injection has not been studied in children. As with all parenteral iron preparations the absorption of oral iron is reduced when administered concomitantly.

DRUG INTERACTIONS: As with all parenteral iron preparations the absorption of oral iron is reduced when administered concomitantly. Therefore, if required, oral iron therapy should not be started

for at least 5 days after the last injection of Ferric Carboxymaltose.

ADVERSE REACTIONS: anaphylactoid reactions, Hypersensitivity, Headache, dizziness, Paraesthesia, dysgeusia, loss of consciousness, Anxiety, tachycardia, Hypertension, flushing, Phlebitis, syncope, presyncope, Dyspnoea, Bronchospasm, Nausea, Vomiting, dyspepsia, abdominal pain, constipation, diarrhea, flatulence, Pruritus, urticaria, erythema, rash, Angioedema, pallor, and face oedema, Myalgia, back pain, arthralgia, muscle spasm, Pyrexia, fatigue, chest pain, oedema peripheral, chills, Rigors, malaise, influenza like illness, Hypophosphataemia.

MARKETED BY:

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IN/REDULID FCM 50 mg/Aug-2023/01/ABPI
(Additional information is available on request)