Information For the Use

Ferric Carboxymaltose (500mg)

Feryskol FCM Injection

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Composition:
Each vial contains:

- **Ferric Carboxymaltose: 500 mg (equivalent to elemental iron).**

Description:
Ferric Carboxymaltose is a non-dextran, intravenous iron formulation used to treat iron deficiency states. It ensures rapid replenishment of iron stores with a lower risk of hypersensitivity reactions compared to older formulations.

Indications:
Ferric Carboxymaltose Injection is indicated for:

- **Iron Deficiency Anemia (IDA):**
  - **In adults and adolescents ≥12 years when oral iron therapy is ineffective or cannot be tolerated.**
  - **Associated with chronic diseases such as chronic kidney disease (CKD), inflammatory bowel disease, or heavy uterine bleeding.**
- **Perioperative Anemia: In patients undergoing elective surgeries to optimize hemoglobin levels.**
- **Postpartum Anemia: For rapid iron replenishment in postpartum women.**

Mechanism of Action:
Ferric Carboxymaltose consists of iron bound to a carbohydrate polymer. After intravenous administration, it is taken up by macrophages and releases iron into the bloodstream. This iron is incorporated into hemoglobin, myoglobin, and other iron-dependent enzymes.

Dosage and Administration:

- **The dose depends on the patient's iron deficiency level.**
- **Typical Dosing:**
  - **500 mg can be administered per session, with a maximum of 1000 mg per week.**
- **Administered as:**
  - **Intravenous Bolus Injection: 500 mg over at least 4-6 minutes.**
  - **Intravenous Infusion: Dilute in 100-250 ml of 0.9% saline; administer over 15-30 minutes.**
- **Total iron requirement is calculated using the Ganzoni formula or based on clinical judgment.**

Contraindications:

- **Hypersensitivity to Ferric Carboxymaltose or its components.**
- **Iron overload disorders (e.g., hemochromatosis).**
- **Anemia not attributed to iron deficiency (e.g., megaloblastic anemia).**

Precautions:

- **Allergic Reactions: Monitor for signs of hypersensitivity during and after administration.**
- **Hepatic and Renal Impairment: Use cautiously in patients with significant liver or kidney dysfunction.**
- **Monitoring: Assess ferritin, hemoglobin, and transferrin saturation levels periodically to avoid iron overload.**
- **Pregnancy and Lactation:**
  - **Pregnancy Category B: Use only if clearly needed during the second and third trimesters.**
  - **Lactation: Limited data suggest low iron transfer into breast milk.**

Possible Side Effects:
Common side effects:

- **Nausea, vomiting, or abdominal discomfort.**
- **Injection site reactions (pain, swelling).**
- **Headache, dizziness, or flushing.**

Serious side effects:

- **Hypersensitivity Reactions: Includes rash, itching, or anaphylaxis (rare).**
- **Iron Overload: Symptoms include joint pain, fatigue, or darkened skin.**

Drug Interactions:

- **Avoid concurrent administration with oral iron, as it reduces absorption of oral forms.**
- **Use cautiously with medications that may exacerbate hypersensitivity reactions.**

Storage:

- **Store at 15°C to 25°C.**
- **Protect from light and freezing.**
- **Use immediately after opening.**

Special Instructions:

- **This medication is for intravenous use only and should be administered by trained healthcare professionals.**
- **Ensure emergency equipment is readily available to manage hypersensitivity reactions.**
- **Discontinue use if signs of iron overload or intolerance occur.**

Note: Regular follow-ups are essential to monitor the effectiveness of therapy and to avoid iron overload. Ensure adherence to prescribed dosage and frequency.

Manufactured in India for:

Cafoli™ LIFECARE

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(An ISO 9001: 2015 Certified Co.)
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