Information For the User Elemental Iron (20mg) Feryskol Injection

Elemental Iron (20mg) Injection

Composition:

Each 1 mL of the injection contains:

• Elemental Iron: 20 mg (as Iron Dextran or similar complex)

Pharmacological Class:

• Iron Supplement / Hematinic

Indications:

This injection is indicated for the treatment of iron deficiency anemia in patients who are unable to take oral iron supplements or in situations where rapid replenishment of iron is required. It is typically used in:

- Severe Iron Deficiency Anemia: When oral iron supplementation is ineffective, poorly tolerated, or contraindicated.
- Chronic Blood Loss: For patients with conditions like gastrointestinal bleeding, heavy menstruation, or other chronic bleeding disorders.
- Preoperative and Postoperative Management: To increase iron levels in patients undergoing surgery who may have low iron stores.
- Malabsorption Conditions: In patients with conditions such as celiac disease, inflammatory bowel disease, or after bariatric surgery, where iron absorption is impaired.

Mechanism of Action:

Iron is an essential component of hemoglobin, the protein in red blood cells that carries oxygen throughout the body. Iron supplementation works by replenishing iron stores, improving hemoglobin synthesis, and helping to restore the body's ability to produce red blood cells. Once administered, elemental iron is incorporated into hemoglobin, improving oxygen transport and alleviating the symptoms of iron deficiency anemia.

Dosage and Administration:

- The typical dosage is 20 mg of elemental iron per mL, which is usually administered by intramuscular (IM) or intravenous (IV) injection.
- Adults and Children Over 12 Years: The dose and frequency depend on the severity of the iron deficiency and the healthcare provider's recommendation. Typically, 1 to 2 injections may be required weekly, depending on the patient's iron levels and response to treatment.
- For IV administration, the injection should be administered slowly to avoid adverse reactions.
- For IM injection, it should be injected deeply into a muscle, avoiding veins.
- The total dose needed to replenish iron stores will depend on the degree of deficiency and the individual patient's needs.
- Dosage adjustments may be made based on patient response and laboratory iron levels.

Contraindications:

- Hypersensitivity to Iron Dextran or other iron preparations: This product should not be used in patients with a known allergy to iron or any component of the formulation.
- Iron Overload: This product is contraindicated in patients with conditions such as hemochromatosis, hemosiderosis, or any form of iron overload.
- Anemia Not Caused by Iron Deficiency: The injection should not be used in cases where anemia is not due to iron deficiency, such as hemolytic anemia or anemia caused by blood loss from other sources.

Warnings and Precautions:

- Iron Overload Risk: Care should be taken not to exceed the recommended dosage, as excessive iron can lead to iron toxicity, which can cause serious damage to organs like the liver and heart.
- Hypersensitivity Reactions: Anaphylactic or allergic reactions to iron injections can occur, although rare. Patients should be monitored

closely during the injection, and emergency measures should be available in case of severe allergic reactions.

- Hypotension: Slow intravenous administration is recommended to prevent a drop in blood pressure during the injection.
- Gastrointestinal Conditions: Patients with active gastrointestinal ulcers or other significant gastrointestinal issues should use iron injections cautiously, as it can worsen certain conditions.
- Pregnancy and Lactation: Iron injections are generally considered safe during pregnancy and breastfeeding when used as prescribed by a healthcare provider. However, the risks and benefits should be evaluated on an individual basis.

Side Effects:

- Common Side Effects:
 - Pain, swelling, or irritation at the injection site (especially with IM injection)
 - Nausea or mild gastrointestinal discomfort
 - Temporary darkening of stools (indicating the presence of iron)
 - Low blood pressure (especially with rapid IV infusion)
 - Dizziness or headache
 - **Rare but Serious Side Effects:**
 - Allergic reactions, including rashes, itching, or difficulty breathing (anaphylaxis)
 - Fever or chills following the injection
 - Metallic taste or mouth irritation
 - Iron overload symptoms (e.g., joint pain, abdominal discomfort, or heart problems in cases of excessive dosing)

Drug Interactions:

- Antacids and Calcium Supplements: These can reduce the absorption of iron when taken together. It is recommended to separate the administration of iron injections from these products by at least 2 hours.
- Tetracycline Antibiotics: Iron can reduce the absorption of certain antibiotics like tetracyclines. It is advised to space their administration by at least 2 hours.
- Other Iron Preparations: Concurrent use of other iron supplements may increase the risk of iron overdose.

 Blood Pressure Medications: Caution should be exercised when administering iron injections to patients on blood pressure medications, as iron may cause fluctuations in blood pressure.

Storage:

- Store at room temperature (between 20°C to 25°C) in a cool, dry place, away from direct sunlight.
- Do not freeze.
- Keep the product out of reach of children.

Packaging:

• Available in multi-dose vials or single-dose ampoules containing 1 mL or 2 mL of injection.

Manufacturer:

• [Manufacturer Name]

Note:

Iron injections should only be administered by a trained healthcare professional due to the risk of adverse reactions. It is important to monitor iron levels regularly during treatment, as excessive iron can be harmful. This product should not be used to treat anemia caused by any condition other than iron deficiency unless specifically advised by a healthcare provider.

Manufactured in India for:

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