Revofer™ Injection

Ferric Carboxymaltose INN

COMPOSITION

Revofer™ 500 IV Injection: Each 10 ml contains Ferric Carboxymaltose INN equivalent to elemental Iron 500 mg.
Revofer™ 750 IV Injection: Each 15 ml contains Ferric Carboxymaltose INN equivalent to elemental Iron 750 mg.

PHARMACOLOGY

Ferric Carboxymaltose is a colloidal iron (III) hydroxide in complex with carboxymaltose, a carbohydrate polymer that releases iron.

INDICATION

Revofer™ is indicated for the treatment of iron deficiency anemia in adult patients:
•who have intolerance to oral iron or have had unsatisfactory response to oral iron
•who have non-dialysis dependent chronic kidney disease.

DOSAGE AND ADMINISTRATION

•For patients weighing 50 kg (110 lb) or more: **Revofer**™ should be given in two doses separated by at least 7 days. Each dose should be given as 750 mg for a total cumulative dose not to exceed 1500 mg of iron per course.
•For patients weighing less than 50 kg (110 lb): **Revofer**™ should be given in two doses separated by at least 7 days. Each dose should be given as 15 mg/kg body weight for a total cumulative dose not to exceed 1500 mg of iron per course.

METHOD OF ADMINISTRATION

Revofer™ must be administered only by the intravenous route: by bolus injection or by infusion. It must be diluted only in sterile 0.9% Sodium Chloride solution as shown in the below table:
Dilution plan of **Revofer**™ for Intravenous Infusion:

Volume of Revofer™	Equivalent Iron Dose	Maximum amount of Sterile 0.9% Sodium Chloride solution	Minimum Administration Time
10 ml	500 mg	100 ml	6 minutes
15 ml	750 mg	250 ml	15 minutes

CONTRAINDICATION

• hypersensitivity to the active substance
• known serious hypersensitivity to other parenteral iron products
• anemia not attributed to iron deficiency, e.g. other microcytic anemia
• evidence of iron overload or disturbances in the utilisation of iron

PRECAUTION

Hypersensitivity Reactions: Parenterally administered iron preparations can cause hypersensitivity reactions including serious and potentially fatal anaphylactic reactions. Hypersensitivity reactions have also been reported after previously uneventful doses of parenteral iron complexes.
Hypertension: Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed. These elevations generally occurred immediately after dosing and resolved within 30 minutes.
Laboratory Test Alterations: In the 24 hours following administration of Ferric Carboxymaltose, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in Ferric Carboxymaltose.

SIDE EFFECT

The most common side effects of Ferric Carboxymaltose include nausea, high blood pressure, flushing, low levels of phosphorous in blood, dizziness, vomiting, headache and pain or bruising at the injection site.

DRUG INTERACTION

The absorption of oral iron is reduced when administered concomitantly with parenteral iron preparations. Therefore, if required, oral iron therapy should not be started for at least 5 days after the last administration of Ferric Carboxymaltose.

USE IN PREGNANCY AND LACTATION

Pregnancy: There are limited data from the use of **Revofer**™ in pregnant women. A careful benefit/risk evaluation is required before use during pregnancy and Ferric Carboxymaltose should not be used during pregnancy unless clearly necessary. Lactation: Ferric Carboxymaltose is excreted in human milk which is unlikely to affect the baby.

PEDIATRIC USE

Ferric Carboxymaltose is not recommended in children less than 14 years.

OVERDOSE

Administration of Ferric Carboxymaltose in quantities exceeding the amount needed to correct iron deficit at the time of administration may lead to accumulation of iron in storage sites eventually leading to hemosiderosis.

STORAGE CONDITION

Store below 30^0C, protected from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Revofer™ 500 IV Injection: Each box contains one vial of 10 ml Ferric Carboxymaltose solution with one 100 ml 0.9% Sodium Chloride solution, Infusion Set, First Aid Bandage, Alcohol Pad & 10 ml sterile Disposable Syringe.
Revofer™ 750 IV Injection: Each box contains one vial of 15 ml Ferric Carboxymaltose solution with one 250 ml 0.9% Sodium Chloride solution, Infusion Set, First Aid Bandage, Alcohol Pad & 10 ml sterile Disposable Syringe.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH