# Ferijet

Iron (as Ferric Carboxymaltose INN)

## COMPOSITION

**Ferijet 500 mg IV Injection:** Each vial contains Ferric Carboxymaltose INN equivalent to 500 mg elemental Iron.

## PHARMACOLOGY

Ferric Carboxymaltose is a colloidal Iron (III) Hydroxide in complex with Carboxymaltose, a carbohydrate polymer that releases Iron.

## INDICATION

It is an iron replacement product 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

## DOSAGES & ADMINISTRATION

***For patients weighing 50 kg (110 lb) or more:*** Give in two doses separated by at least 7 days. Give each dose as 500 mg for a total cumulative dose of 1000 mg of iron per course.

***For patients weighing less than 50 kg (110 lb):*** Give in two doses separated by at least 7 days and give each dose as 15 mg/kg body weight for a total cumulative dose not to exceed 1000 mg of Iron per course. Administer **Ferijet** intravenously, either as an undiluted slow intravenous push or by infusion. When administering as a slow intravenous push, give at the rate of approximately 100 mg (2 ml) per minute. When administered via infusion, dilute with sterile 0.9% Sodium Chloride injection, such that the concentration of the infusion is not less than 2 mg of iron per ml and administer over at least 15 minutes. When added to an infusion bag containing 0.9% Sodium Chloride Injection, at concentrations ranging from 2 mg to 4 mg of iron per ml, **Ferijet** solution is physically and stable for 72 hours when stored at room temperature. To maintain stability, do not dilute to concentrations less than 2 mg iron/ml.

***Determination of the iron need***

The individual iron need for repletion using **Ferijet** is determined based on the patient's body weight and hemoglobin (Hb) level (see Table 1):

**Table-1: Determination of the Iron need:**

| Hemoglobin (Hb) | | Patient body weight | | |
|---|---|---|---|---|
| g/dL | mmol/L | below 35 kg | 35 kg to ≤70 kg | Over 70 kg |
| <10 | <6.2 | 500 mg | 1,500 mg | 2,000 mg |
| 10 to 14 | 6.2 to <8.7 | 500 mg | 1,000 mg | 1,500 mg |
| >14 | ≥8.7 | 500 mg | 500 mg | 500 mg |

Iron deficiency must be confirmed by laboratory tests.

Calculation and administration of the maximum individual iron dose(s) on the iron need determined above the appropriate dose(s) of **Ferijet** should be administered taking into consideration the following:

A single **Ferijet** administration should not exceed:

- 15 mg iron/kg body weight (intravenous injection) or 20 mg iron/kg body weight (intravenous infusion)
- 1000 mg of iron (20 ml **Ferijet**)

The maximum recommended cumulative dose of **Ferijet** is 1000 mg of iron (20 ml **Ferijet**) per week. A single maximum daily dose of 200 mg iron should not be exceeded in haemodialysis-dependent chronic kidney disease patients.

**Method of administration**

**Ferijet** must only be administered by the intravenous route: by injection, by infusion, or during a hemodialysis session undiluted directly into the venous limb of the dialyzer. **Ferijet** must not be administered by the subcutaneous or intramuscular route.

***Intravenous injection***

**Ferijet** may be administered by intravenous injection using undiluted solution. The maximum single dose is 15 mg iron/kg body weight but should not exceed 1000 mg iron. The administration rates are as shown in Table 2.

**Table 2: Administration rates for intravenous injection of Ferijet**

| Volume of Ferijet required | Equivalent iron dose | Administration rate/ Minimum administration time |
|---|---|---|
| 2 to 4 ml | 100 to 200 mg | No minimal prescribed time |
| >4 to 10 ml | >200 to 500 mg | 100 mg iron/min |
| >10 to 20 ml | >500 to 1000 mg | 15 minutes |

**Intravenous infusion**

**Ferijet** may be administered by intravenous infusion, in which case it must be diluted. The maximum single dose is 20 mg iron/kg body weight but should not exceed 1,000 mg iron. **Ferijet** must only be diluted in sterile 0.9% Sodium Chloride Solution as shown in Table 3. Note: for stability reasons, **Ferijet** should not be diluted to concentrations less than 2 mg iron/ml (not including the volume of the Ferric Carboxymaltose solution).

**Table 3: Dilution plan of Ferijet for intravenous infusion**

| Volume of Ferijet required | Equivalent iron dose | Maximum amount of sterile 0.9% Sodium Chloride Solution | Minimun administration time |
|---|---|---|---|
| 2 to 4 ml | 100 to 200 mg | 50 ml | No minimal prescribed time |
| >4 to 10 ml | >200 to 500 mg | 100 ml | 6 minutes |
| >10 to 20 ml | >500 to 1000 mg | 250 ml | 15 minutes |

***Monitoring measures***

Reassessment should be performed by the clinician based on the individual patient's condition. The Hb level should be reassessed no earlier than 4 weeks post final **Ferijet** administration. If the patient requires further iron repletion, the iron need should be recalculated using Table 1.

***Incompatibilities***

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 **Ferijet**.

***Instructions for Handling and Disposal***

Inspect vials visually for sediment and damage before use. Each vials of Ferric Carboxymaltose is intended for single use only. Any unused product or waste material should be disposed of in accordance with local requirements. Ferric Carboxymaltose must only be mixed with sterile 0.9% Sodium Chloride Solution. No other intravenous dilution solutions and therapeutic agents should be used, as there is the potential for precipitation and/or interaction.

## CONTRAINDICATION

Hypersensitivity to Ferric Carboxymaltose injection or any of its components.

## SIDE-EFFECT

Nausea, hypertension, flushing, hypophosphatemia, dizziness etc.

## PRECAUTION AND WARNING

Observe signs and symptoms of hypersensitivity during and after this injection administration for at least 30 minutes and until clinically stable following completion of each administration. Monitor patients closely for signs and symptoms of hypertension following each injection administration.

## USE IN PREGNANCY & LACTATION

***Pregnancy:*** Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect effects on human fetus having been observed. Studies in animals have shown evidence of an increased occurrence of fetal damage, the significance of which is considered uncertain in humans.

***Breastfeeding:*** Clinical studies showed that transfer of iron from Ferric Carboxymaltose to human milk was negligible. Based on limited data on breastfeeding women it is unlikely that Ferric Carboxymaltose represents a risk to the breastfed child.

***Fertility:*** There is no data on the effect of Ferric Carboxymaltose on human fertility. Fertility was unaffected following Ferric Carboxymaltose treatment in animal studies.

## USE IN CHILDREN AND ADOLESCENTS

The use of Ferric carboxymaltose has not been studied in children and therefore is not recommended in children under 14 years.

## DRUG INTERACTION

Formal drug interaction studies have not been performed with Ferric carboxymaltose.

## OVERDOSE

Administration of **Ferijet** 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. Monitoring of iron parameters such as serum ferritin and transferrin saturation may assist in recognizing iron accumulation. If iron accumulation has occurred, treat according to standard medical practice, e.g. consider the use of an iron chelator.

## STORAGE CONDITION

- Store below 30°C, keep in dry place & protect from light.
- Keep out of reach of children.

## PACKAGING

**Ferijet 500 mg IV Injection:** Each box contains one vial of 10 ml Ferric Carboxymaltose solution with one 100 ml normal saline (Sodisol), one infusion set, one alcohol pad, one first aid band, one disposable syringe (10 ml) and one hanger.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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