IV iron

Essential Prescription and Administration Information to Minimize the Risk of Serious Hypersensitivity Reactions

This educational material is intended to Health care providers (HCPS) to:

- ✓ Ensure the safe and effective use of different IV Iron medicinal products and minimizing the risk of confusion between different IV iron products to prevent inadvertent harm, especially the hypersensitivity reactions.

Dear HCP it is advised to read carefully and review the following before prescribing or dispensing or administering the IV Iron medicinal products

Before each administration of IV iron, you should inform your patient so that they are aware that…

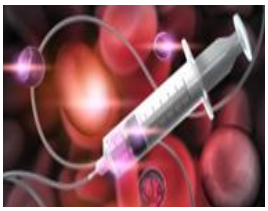
- Parenterally administered iron preparations can cause hypersensitivity reactions including serious and potentially fatal anaphylactic/anaphylactoid reactions.
- These reactions have also been reported after previously uneventful doses of IV iron.
- **They may have an increased risk of experiencing a hypersensitivity reaction if they have:**
  known allergies including drug allergies*, a history of severe asthma*, eczema* or other atopic allergies *or immune or inflammatory conditions (e.g., rheumatoid arthritis, lupus erythematosus) *.

***In these patients, IV iron products should only be used if the benefit is clearly judged to outweigh the potential risk**

- IV iron should not be used during pregnancy unless clearly necessary. Treatment should be confined to the 2nd–3rd trimester if the benefit is judged to outweigh the potential risk for both the mother and the foetus.

- They should report any signs or symptoms suggestive of a hypersensitivity reaction (e.g.: hives, pruritus, dyspnoea, wheezing, swelling of the lips, tongue, throat, or body) to their doctor /nurse immediately.

Remember that IV iron is contraindicated and should not be administered if your patient:



- Has known hypersensitivity to the IV iron product, the active substance or to any of its excipients.
- Has previously experienced a serious hypersensitivity reaction to any IV iron preparations.
- Has anaemia not caused by iron deficiency.
- Has evidence of iron overload or disturbances in the utilisation of iron.
- In patients with liver dysfunction, parenteral iron should only be administered after careful risk/benefit assessment.

Before each administration of IV iron make sure that:

- Staff trained to evaluate and manage anaphylactic reactions are immediately available.
- Cardio-pulmonary resuscitation facilities and equipment for handling acute anaphylactic /anaphylactoid reactions, including an injectable 1:1000 adrenaline solution, are immediately available onsite.
- Additional treatment with antihistamines and/or corticosteroids should be given as appropriate.

During administration of IV iron remember that:

- If hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be stopped immediately, and appropriate management initiated.
- **IV Iron Products should be administered in accordance with the posology and method of administration described in the product information for each individual product.**

After you have administered IV Iron:

- The patient must be closely observed for signs and symptoms of hypersensitivity reactions for at least 30 minutes after each administration.

See the Summary of Product Characteristics (Leaflet) of individual IV iron medicinal products for full product information, to minimize the Risk of Serious Hypersensitivity Reactions.

Product choice

Different injectable (IV) iron products may differ in:

- ✓ Iron slat, molecular weight
- ✓ Strength
- ✓ Dose
- ✓ Administration route
- ✓ Administration method
- ✓ Administration rate
- ✓ Manufacturer safety information

Preparation and administration are product specific and should referred to the specific product leaflet/SmPC information

Reporting of suspected adverse reactions; please make sure to report the trade name of the actual product being used by using:

- ✓ email: jpc@jfda.jo
- ✓ website: https://vigiflow-eforms.who-umc.org/jo/jpc
- ✓ Phone No: +962-6-5632000
- ✓ QR Code:

Annex I

IV Iron Preparations Registered in Jordan for Treatment of Iron Deficiency

Please refer to the product information leaflet for full information related to indications, contraindications, warnings, dose and method of administration ….

1- Iron Dextran

CosmoFer 50mg/ml solution for infusion and injection

For full information go back to the latest SmPC approved by JFDA

Administration:

Intravenous drip infusion:

Iron dextran must be diluted only in 0.9% sodium chloride solution (normal saline) or in 5% glucose solution. Iron dextran in a dose of 100-200 mg iron (2-4ml) may be diluted in 100 ml. **On each occasion the first 25 mg of iron should be infused over a period of 15 minutes**. If no adverse reactions occur during this time the remaining portion of the infusion should be given at an infusion rate of not more than 100 ml in 30 minutes.

Intravenous injection:

Iron dextran may be administered in a dose of 100 – 200 mg iron (2-4 ml) by slow intravenous injection (0.2 ml/min) preferably diluted in 10 – 20 ml 0.9% sodium chloride or 5% glucose solution. **On each occasion before administering a slow intravenous injection, 25 mg of iron should be injected slowly over a period of 1 to 2 minutes.** If no adverse reactions occur within 15 minutes, the remaining portion of the injection may be given.

2- Iron Sucrose

Venofer 20 mg/mL, solution for injection or concentrate for solution for infusion.

Other trade names of products containing Iron Sucrose that are registered with the JFDA

Ferrasil®, Ferrovin®, Feradeed®, Feromax®

For full information go back to the latest SmPC approved by JFDA

Administration: iron sucrose must only be administered intravenously by drip infusion, by slow injection or directly into the venous line of the dialysis machine.

Intravenous drip infusion

Venofer must only be diluted in sterile 0.9% m/V sodium chloride (NaCl) solution. Dilution must take place immediately prior to infusion and the solution should be administered as follows:

Venofer dose (mg of iron)	Venofer dose (mL of Venofer)	Maximum dilution volume of sterile 0.9% m/V NaCl solution	Minimum Infusion Time
50 mg	2.5 mL	50 mL	8 minutes
100 mg	5 mL	100 mL	15 minutes
200 mg	10 mL	200 mL	30 minutes

For stability reasons, dilutions to lower Venofer concentrations are not permissible.

	Intravenous injection Venofer may be administered by slow intravenous injection at a rate of 1 mL undiluted solution per minute and not exceeding 10 mL Venofer (200 mg iron) per injection.

3-	Ferric Carboxymaltose
Ferinject 50 mg/mL dispersion for injection/infusion.  For full information go back to the latest SmPC approved by JFDA	**Administration:** Intravenous injection Ferinject may be administered by intravenous injection using undiluted dispersion. In adults and adolescents aged 14 years and older, the maximum single dose is 15 mg iron/kg body weight but should not exceed 1,000 mg of iron. In children aged 1 to 13 years, the maximum single dose is 15 mg iron/kg body weight but should not exceed 750 mg of iron. The administration rates are as shown in Table below:

Volume of Ferinject 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 1,000 mg	15 minutes

Intravenous infusion

Ferinject may be administered by intravenous infusion, in which case it must be diluted. In adults and adolescents aged 14 years and older, the maximum single dose is 20 mg iron/kg body weight but should not exceed 1,000 mg of iron. In children aged 1 to 13 years, the maximum single dose is 15 mg iron/kg body weight but should not exceed 750 mg of iron.

For infusion, Ferinject must only be diluted in sterile 0.9% m/V sodium chloride solution.

Dilution plan of Ferinject for intravenous infusion

Volume of Ferinject required	Equivalent iron dose	Maximum amount of sterile 0.9% m/V sodium chloride solution	Minimum 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 1,000 mg	250 mL	15 minutes

Note: The names of the listed products are subject to change according to their registration status at the JFDA.