Feromax important HCP information

Objective of this educational material:
This educational material is essential to ensure the safe and effective use of the product and appropriate management of the important selected risks.

It is advised to be read carefully before prescribing or dispensing or administering the product.

FEROMAX Injection▼
Essential Prescription and Administration Information to Minimise the Risk of Serious Hypersensitivity Reactions (iron sucrose)

Please read carefully and review each time when prescribing FEROMAX or any other IV iron medicinal products.

BEFORE each administration of, FEROMAX or any other 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, FEROMAX or any other IV iron 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.
- The patient should also be given a copy of the patient information leaflet provided with the individual IV iron product to be administered.

Remember that **FEROMAX or any other 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.

See the Summary of Product Characteristics of **FEROMAX Injection or any other IV iron** medicinal products for full product information.

BEFORE each administration of FEROMAX or any other 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 FEROMAX or any other IV iron remember that:

- if hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be **stopped immediately**, and appropriate management initiated.
- **FEROMAX** 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 FEROMAX:

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

Method of Administration:

- Feromax must only be administered by the intravenous route. This may be by a slow intravenous injection, by an intravenous drip infusion or directly into the venous line of the dialysis machine.
- Intravenous drip infusion
  - Feromax 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:

Feromax dose (mg of iron)	Feromax dose (ml of Feromax)	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 Feromax concentrations are not permissible.
- Intravenous injection Feromax may be administered by slow intravenous injection at a rate of 1 ml undiluted solution per minute and not exceeding 10 ml Feromax (200 mg iron) per injection.
- Injection into venous line of dialysis machine Feromax may be administered during a haemodialysis session directly into the venous line of the dialysis machine under the same conditions as for intravenous injection.

Intravenous (IV) iron medicinal products are subject to additional monitoring.

- Parenterally administered iron medicinal products are used to treat iron deficiency when oral preparations are ineffective or cannot be used.
- Parenterally administered iron preparations can cause hypersensitivity reactions including serious and potentially fatal anaphylactic /anaphylactoid reactions.
  This essential prescription information guide can assist you in managing and minimising this risk.

Contraindications to the use of FEROMAX include:

- hypersensitivity to the active substance or any of its excipients.
- known serious hypersensitivity to other parenteral iron products.
- anaemia not caused by iron deficiency
- evidence of iron overload or disturbances in the utilisation of iron.
  See the Summary of Product Characteristics of individual IV iron medicinal products for full product information.

Reporting of suspected adverse reactions FEROMAX are subject to additional monitoring. This will allow quick identification of new safety information.
Healthcare professionals are asked to report any suspected adverse reactions to the Gulf pharmaceutical industries or the National Pharmacovigilance and Drug Safety Center.
To report any side effect(s):

- The National Pharmacovigilance and Drug Safety Centre (NPC): Fax: +966-11-205-7662
  SFDA Call Center: 19999 E-mail: npc.drug@sfda.gov.sa Website: https://ade.sfda.gov.sa
- Gulf Pharmaceutical Industries (Julphar): Call Julphar at: +966114631299
  E-mail:medical.affairs@julphar.net You can also report any side effects directly via the following link:
  https://www.julphar.net/en/pharmacovigilance/how-do-i-report-an-adverse-