Feromax important patient 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.

FEROMAX Injection (iron sucrose) ▼ Important Information for Patients about the Possible Risk of Serious Allergic Reactions with FEROMAX or any IV iron treatment (iron given by injection or infusion into a vein) iron sucrose
Please read this leaflet carefully and discuss any questions you may have with your Doctor.
You should also read the patient information leaflet that comes with FEROMAX Injection. This contains important additional information regarding the medicine.

FEROMAX Injection is used to treat iron deficiency when iron preparations taken by mouth have not worked or cannot be used. The aim of treatment is to replenish the body's iron stores.

IV Iron can cause allergic reactions. In a small number of patients these allergic reactions can become severe or life-threatening (known as anaphylactic reactions) and can cause problems with your heart and blood pressure and/or cause you to faint or lose consciousness.

You should not be prescribed or given FEROMAX Injection if:

- **you are allergic (hypersensitive) to the product or any of the other ingredients of this medicine**
- **you have experienced serious allergic (hypersensitive) reactions to other IV iron treatments in the past***
- **you have iron overload (too much iron in your body)**
- **your anaemia is not caused by iron deficiency**

You should tell your doctor before they prescribe/administer FEROMAX Injection if you have any of these allergies or conditions.

*** It is important to know that a reaction can still happen even if you have not had any problems in the past with IV iron.**

You may have an increased risk of having an allergic reaction if you have:

- **known allergies including drug allergies**
- **a history of severe asthma, eczema, or other allergies (for example dust, pollen, pet dander) or**
- **immune or inflammatory conditions (e.g., rheumatoid arthritis, lupus erythematosus) or**

- **liver problem**

You should tell your doctor before they prescribe or give you FEROMAX Injection if you have any of these allergies or conditions. Your Doctor will decide whether IV iron is suitable for you.

Pregnancy:

- FEROMAX should not be used during pregnancy unless clearly necessary. If you are pregnant or think you could be pregnant or are planning to have a baby. it is important to discuss this with your doctor.
- If you become pregnant during treatment, you must ask your doctor for advice. Your doctor will decide whether you should be given this medicine or not.

You should contact your Doctor or Pharmacist or Nurse immediately if:

You have any signs or symptoms of an allergic reaction during or shortly after treatment with IV Iron

For example, hives or rash, itching, dizziness, light-headedness, swelling of the lips, tongue, throat or body, difficulty breathing, shortness of breath or wheezing.

Your doctor and nursing staff are aware of these possible side effects, and you will be monitored during and after you receive FEROMAX or any IV iron treatment.

Reporting of suspected adverse reactions

These medicines are subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side affects you may get. If you get any side effects, talk to your Doctor or nurse. This includes any possible side effects even if they are not listed in this leaflet. You can also report side effects directly to 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-reaction