

Pregnancy: IV iron should not be used during pregnancy unless clearly necessary. If you are pregnant or think you could be pregnant, it is important to discuss this with your doctor.

You should contact your Doctor 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 IV iron.

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 effects 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 as following:

- Call at +966114623647 fax: +966114659921 or e.mail us at medical.affairs@julphar.net

- The National Pharmacovigilance and Drug Safety Center (NPC):
<https://ade.sfda.gov.sa>
E-mail: npc.drug@sfda.gov.sa
Call NPC at +966-11-2038222 Ext: 5729, 2356, 2317, 2340

Intravenous (IV) Iron ▼

Important Information for Patients about the Possible Risk of Serious Allergic Reactions with IV iron treatment (iron given by injection or infusion into a vein)

ferric carboxymaltose, iron dextran, iron isomaltoside 1000, 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 the particular IV iron that you have been prescribed. This contains important additional information regarding the medicine.

IV Iron 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 an IV Iron 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 an IV Iron 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)

You should tell your doctor before they prescribe or give you IV Iron if you have any of these allergies or conditions.

Your Doctor will decide whether IV iron is suitable for you.