

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed within the patient information leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine. Side effects can also be reported to the marketing authorisation holder:

Rowex Ltd.,
Bantry,
Co. Cork,
Ireland.
e-mail: pv@rowa-pharma.ie
Tel: 027 50077

IV Iron is used to treat iron deficiency when oral preparations are ineffective or cannot be used.

IV Iron can cause allergic reactions and must be administered by persons trained to evaluate and manage these reactions.

In some 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.

Intravenous (IV) Iron

Important Information for Patients

About the Possible Risk of Serious

Allergic Reactions with IV iron

**(medication given by needle into the
vein)**

This information has been prepared and provided to you by Rowex Ltd.

Please read this leaflet carefully and discuss any questions you may have with your Doctor.

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 and others)

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

Your Doctor will decide whether the benefit to you is greater than the risk.

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 or nurse 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.**

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 or nurse will monitor you for signs and symptoms of an allergic reaction for at least 30 minutes after each time IV iron is given to you.