Further to the European Medicine Agency (EMA) referral, IV iron medicinal products are under additional monitoring. The EMA considers the benefit / risk of IV iron products favourable when oral route is insufficient or poorly tolerated.

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 IV iron 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.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Reporting adverse drug reaction is mandatory by law and allows continued monitoring of the benefit / risk balance of the medicinal product. Please report any suspect adverse drug reaction to either the marketing authorisation holder (MAH) or to the local regulatory authority according the local requirements in your country. When reporting please ensure to include the name of the specific product administered. The contact details of MAH and local representative are mentioned in the Summary of Product Characteristics as well as Patient Information Leaflet.

You can also report side effects directly via HPRA pharmacovigilance,
Earlsfort Terrace, IRL – Dublin 2,
Tel: +353 1 6764971, Fax: +353 1 67625177836,
Website: www.hpra.ie, e-mail: medsafety@hpra.ie

IV iron ▼

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

This essential prescription information guide is brought to you by the European IV iron suppliers.

Please read carefully and review each time when prescribing 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.

The patient should also be given a copy of the patient information leaflet provided with the individual IV iron product to be administered.

… and 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.

See the Summary of Product Characteristics of individual IV iron medicinal products for full product information.

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 a hypersensitivity reactions for at least 30 minutes after each administration.