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 prescriber guide can assist you in managing and minimising this risk.

Contraindications to the use of IV Ferric Carboxymaltose Teva 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 disturbance in the utilisation of iron

Please refer to the Teva Pharma B.V Ferric Carboxymaltose Teva 50 mg iron/mL Dispersion for Injection/Infusion Summary of Product Characteristics for full product information.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance. Website: www.hpra.ie.

Adverse events may also be reported to Teva Pharmaceuticals Ireland *via* email to:
medinfo@tevauk.com
or by phone on
+44 (0) 207 540 7117.

Teva Pharmaceuticals Ireland,
Digital Office Centre Swords, Suite 101-103,Balheary Demense,Balheary Road, Swords, Co. Dublin, K67E5A. Ireland.

Date of Preparation: July 2024
Date of HPRA Approval: July 2024.

Prescriber Guide for IV Ferric Carboxymaltose Teva

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

This prescriber guide is brought to you by Teva Pharmaceuticals Ireland

Please read carefully and review each time when prescribing IV Ferric Carboxymaltose Teva

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Date of Preparation: July 2024
Date of HPRA Approval: July 2024

BEFORE each administration of IV Ferric Carboxymaltose Teva, 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 parenteral iron complexes
... 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 (systemic lupus emphysematous, rheumatoid arthritis)*.

* In these patients, IV Ferric Carboxymaltose Teva should only be used if the benefit is clearly judged to outweigh the potential risk.

...IV Ferric Carboxymaltose Teva 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 IV Ferric Carboxymaltose Teva

... and remember that IV Ferric Carboxymaltose Teva is contraindicated and should not be administered if your patient...

... has known hypersensitivity to Ferric Carboxymaltose Teva, the active substance or to any of its excipients.

... has previously experienced a serious hypersensitivity reaction to any other parenteral iron preparations.

... has anaemia not caused by iron deficiency.

... has evidence of iron overload or disturbances in the utilisation of iron.

Please refer to the Teva Pharma B.V Ferric Carboxymaltose Teva 50 mg iron/mL Dispersion for Injection/Infusion Summary of Product Characteristics for full product information.

BEFORE each administration of IV Ferric Carboxymaltose Teva make sure that. ..

... staff trained to evaluate and manage anaphylactic reactions are immediately available.

... cardio-respiratory 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 Ferric Carboxymaltose Teva remember that...

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

... IV Ferric Carboxymaltose Teva should be administered in accordance with the posology and method of administration described in the product information

AFTER you have administered IV Ferric Carboxymaltose Teva...

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