HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

New Important Advice to Mitigate the Risk of Serious Hypersensitivity Reactions with Rienso (Ferumoxytol)

Rienso (containing the active substance ferumoxytol) was authorised for the intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease (CKD) in June 2012.

Parenterally administered iron preparations are known to cause hypersensitivity reactions including serious and potentially fatal anaphylactic reactions. Hypersensitivity reactions have also been reported after previously uneventful doses of parenteral iron complexes.

During post-marketing use of Rienso, serious hypersensitivity reactions including anaphylactic reactions, some of which have been life-threatening or fatal, have been reported in patients receiving Rienso. The benefits and risks of Rienso have been evaluated during a routine review in the context of a regular procedure known as a Periodic Safety Update Report (PSUR), which has resulted in new recommendations for use. In order to mitigate the risk of hypersensitivity reactions following use with Rienso, healthcare professionals should be aware of the following new recommendations:

Advice to Healthcare Professionals

- Rienso is contraindicated in patients with any known history of drug allergy including hypersensitivity to other parenteral iron products.
- Rienso should only be administered as an intravenous infusion over a minimum period of 15 minutes and must not be administered by injection (infusion in 50-250 ml of sterile 0.9% sodium chloride or sterile 5% dextrose).
- Rienso should only be administered when staff trained to evaluate and manage anaphylactic reactions as well as resuscitation facilities are immediately available.
- Patients should be placed in a reclined or semi-reclined position during the Rienso infusion and for at least 30 minutes thereafter.
- Patients should be carefully monitored for signs and symptoms of hypersensitivity reactions, including monitoring of blood pressure and pulse, during and for at least 30 minutes after each administration of Rienso.
- Before each administration patients should be informed of the risk of hypersensitivity. Patients should also be informed of the relevant symptoms and asked to seek urgent medical attention if a reaction occurs.
- Any suspected adverse reactions associated with use of Rienso should be reported to the HPRA via the on-line, downloadable or post-paid reporting options (www.hpra.ie).

Key messages

- Rienso is now contraindicated in patients with any known history of drug allergy, including hypersensitivity to other parenteral iron products.
- Rienso should only be administered as an intravenous infusion over a minimum period of 15 minutes and must not be administered by injection (infusion in 50-250 ml of sterile 0.9% sodium chloride or sterile 5% dextrose).
- Rienso should only be administered by staff trained to evaluate and manage anaphylactic reactions and in a setting where resuscitation facilities are immediately available.

Further details on Rienso are available at www.hpra.ie

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