7th August 2014

Rienso ▼ (ferumoxytol) – New important advice to mitigate risk of serious hypersensitivity reactions

Dear Healthcare Professional,

Further to our recent communication of 28th May 2014 in agreement with the European Medicines Agency (EMA) and Medicines and Healthcare products Regulatory Agency (MHRA), Takeda is informing you of the following important changes to the Rienso safety information and mode of administration. These changes are introduced to mitigate the risk of serious hypersensitivity reactions associated with Rienso.

Summary:

- **Rienso is now contraindicated in patients with <u>any known history of drug allergy, including hypersensitivity to other parenteral</u> <u>iron products</u>**
- **Rienso should <u>only</u> be administered as an intravenous infusion in 50-250 ml of sterile 0.9% sodium chloride or sterile 5% glucose over a minimum period of 15 minutes and must not be administered by injection**
- **Patients should be placed in a reclining or semi-reclining position during the Rienso infusion and for at least 30 minutes thereafter**
- **Patients should be carefully monitored for signs and symptoms of hypersensitivity reactions, <u>including monitoring of blood pressure and pulse,</u> during and for at least 30 minutes after infusion. In addition, patients should be instructed to immediately inform their healthcare practitioner if they start to feel unwell**

As previously communicated, Rienso should only be administered by staff trained to recognise and manage anaphylactic reactions in an environment with resuscitation facilities immediately available.

Further background information to this safety update:

Rienso was approved in the European Union in June 2012 for the intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease (CKD). As we advised in our recent communication letter of 28th May 2014, the benefits and risks of Rienso have been evaluated in the context of a regular regulatory procedure known as Periodic Safety Update Report (PSUR), which has now been finalised. This included review of the serious hypersensitivity reactions including life threatening and fatal anaphylactic reactions that have been reported in patients receiving Rienso. On review of the patient and case characteristics in these cases, one notable characteristic was the number of patients that had a known history of drug allergy (i.e. to a non-iron product e.g. antibiotics). In order to mitigate the risk of such hypersensitivity reactions a number of new recommendations are being introduced in the product information, as summarised above.

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Call for reporting

Please continue to report suspected adverse drug reactions to the MHRA through the Yellow Card Scheme. Please report:

- all suspected ADRs that are serious or result in harm. (Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.)
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

It is easiest and quickest to report ADRs online via the Yellow Cards website:

www.mhra.gov.uk/yellowcard

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gsi.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- or by downloading and printing a form from the Yellow Card section of the MHRA website

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name

Contact point

Should you have any questions regarding the use of Rienso or questions about the content of this letter, please contact Takeda UK Ltd:

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Yours sincerely,

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