PRODUCT RECALL

▼ Rienso (Ferumoxytol) 30mg/ml Solution for Infusion
EU/1/12/774/001-004

	Pack Size	Batch Number	Expiry Date
Rienso 30mg/ml	**6 vials**	**240675**	**31/08/15**
Rienso 30mg/ml	**1 vial**	**240789**	**31/08/15**
Rienso 30mg/ml	**1 vial**	**257893**	**31/10/16**
Rienso 30mg/ml	**1 vial**	**290707**	**31/10/16**

12th March 2015

Dear Healthcare Professional/Pharmacist

We wish to advise you that the above-listed batches of Rienso (ferumoxytol) 30mg/ml Solution for Infusion are being recalled, with immediate effect.

This recall is going to wholesale and hospital pharmacy level. This action has been agreed with the Medicines and Healthcare Products Regulatory Agency.

The Marketing Authorisation Holder (MAH) of Rienso, Takeda, has made the decision to withdraw the Marketing Authorisation for the above referenced product in the European Union. This decision has been made for commercial reasons and means that the product will no longer be available for use.

Please quarantine all stock of the above-listed batches on your premises. This includes units at ward level and other relevant locations within the hospital. We kindly ask you to arrange return of the stock immediately (latest by 1st April 2015) to your wholesaler for credit. If you have distributed units from these batches to any other party or to any other hospitals, please contact them so that they may return the units to you.

Please see below for contact details should you have any questions.

Takeda UK Ltd, Building 3, Glory Park Avenue, Wooburn Green, High Wycombe, Bucks, HP10 0DF
Tel: 01628 537900, Fax: 01628 526617, Email: DSO-UK@takeda.com, Website: www.takeda.co.uk

Further information and recommendations for treatment

Rienso is indicated for the intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease (CKD).

Any patient scheduled for administration of Rienso should be referred back to their treating physician for consideration of an alternate IV Iron preparation. No new patients should be prescribed Rienso from the date of this notification.

Call for Adverse Reaction/Event reporting

Please report any suspected adverse reactions (including hypersensitivity) to the MHRA through the Yellow Card Scheme online at www.mhra.gov.uk/yellowcard

Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: "FREEPOST YELLOW CARD"
- 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 electronic download through the Yellow Card section of the MHRA website

When reporting please ensure to include the name of the specific product administered.
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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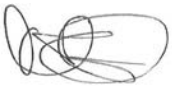
Tel: 01628 537900, Fax: 01628 526617, Email: DSO-UK@takeda.com, Website: www.takeda.co.uk

We thank you for your attention and understanding.

Yours sincerely,



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