08 May 2018

Direct Healthcare Professional Communication

ReoPro® (abciximab) 2 mg/mL solution for injection or infusion – PL 08563/0015: Indefinite Supply Shortage

Dear Healthcare Professional,

Janssen-Cilag Limited would like to inform you of the following:

Summary

- We are facing severe production issues with ReoPro® (abciximab) injection that will result in an indefinite stock out.
- We estimate that hospital pharmacies will be out of stock by June 2018 or earlier.
- Unfortunately, we are unable to make any commitments regarding when the product will return to the market for the foreseeable future.
- Please change your treatment regimen to alternative medications such as other glycoprotein IIb/IIIa antagonists or bivalirudin instead of ReoPro.

Further information
There is no impact to patients who have received ReoPro as the quality of product on the market is not affected.

This stock out occurred because of several issues at a third-party manufacturing site which required significant changes and substantially disrupted the production schedule.

Patient well-being is our primary concern and we wish to apologise for this unfortunate situation. The Company will continue to take every available action to minimise the impact of this stock out. We will also provide status updates if the situation changes.

Call for reporting
Healthcare professionals are reminded to continue to report suspected adverse reactions associated with this product in accordance with the national spontaneous reporting system.

Suspected adverse reactions should be reported to the MHRA through the Yellow Card Scheme: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: “FREEPOST YELLOW CARD” (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the MHRA Yellow Card free phone reporting line: 0800-731-6789
- or by electronic download through 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 dates, treatment dates, product brand name and batch numbers.

Suspected adverse reactions should also be reported to Janssen-Cilag Limited on tel: 01494 567447, fax: 01494 567799 or by email at dsafety@its.jnj.com

Company contact point
If you have further questions or require additional information, please contact:
Janssen-Cilag Limited Medical Information Department:
Email: medinfo@its.jnj.com
Telephone: 0800 731 8450 or 01494 567 444

Yours faithfully,

Dr Frank Wiegand
Medical Director UK & Ireland
Janssen-Cilag Limited