22 September 2017

Direct Healthcare Professional Communication

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

Dear Healthcare Professional,

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

Summary

- There is a temporary interruption of supply for ReoPro® that is likely to result in shortages to patients for the time period between October 2017 and March 2018.
- We estimate that hospital pharmacies will be out of stock by October 2017 or earlier.
- Please consider alternative medications such as other glycoprotein IIb/IIIa antagonists or Bivalirudin instead of ReoPro.

Further information

The shortage occurred because of a supply interruption at our external manufacturer combined with a batch being rejected prior to release.

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

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 supply shortage. 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.

Janssen-Cilag Ltd. 50–100 Holmers Farm Way
High Wycombe Buckinghamshire HP12 4EG England
Telephone: (01494) 567567 Fax: (01494) 567568
Website: www.janssen-cilag.co.uk
Registered in England 1027904

Suspected adverse reactions should be reported to the MHRA through the Yellow Card Scheme: www.mhra.gov.uk/yellowcard

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