

Date: 02 Sep 2021

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

**Bortezomib 2.5mg/ml Solution for Injection (Bortezomib):
Interim Supply of over-labelled Italian stock to Mitigate Supply Disruption**

Dear Healthcare Professional,

Summary: Thornton & Ross Ltd is currently experiencing supply disruption with Bortezomib 2.5mg/ml Solution for Injection (Bortezomib) in the UK.

To ensure continuity in supply, Thornton & Ross Ltd has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to carry out the over-labelling and repackaging of Italian product Bortezomib EG 2,5mg/ml solution for injection (Soluzione iniettabile; batch number ON135E1, batch size 4324 units) with UK information, and supply this stock to the UK market from 13 Sep 2021 to 4 Oct 2021 depending on the consumption.

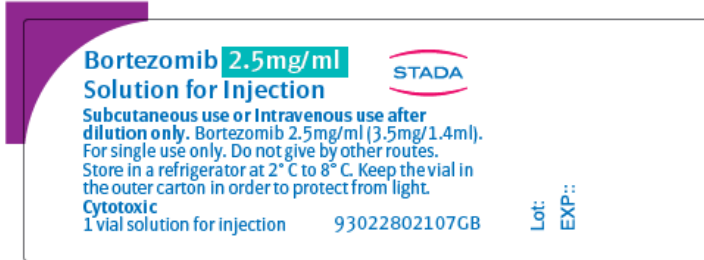
Please note the product may remain on local shelves beyond this date.

Please note the following:

- This product is considered licensed in the UK
- The product from Italy has the same formulation as the UK product
- The product from Italy is manufactured according to the same manufacturing process and quality controls as the UK product
- The Italian product vial label has been over-stickered with UK information and then the vial has been repacked with UK Patient Information Leaflet (PIL) and Carton
- For additional copies of the PIL, please refer to eMC <https://www.medicines.org.uk/emc/product/10201/pil> or contact the company contact point (see below)
The MHRA has approved this product under a batch specific variation to the marketing authorisation.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Images of United Kingdom Bortezomib 2.5mg/ml solution for Injection – Over-sticker Vial Label:



Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <https://www.gov.uk/yellowcard>, the free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#), and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

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

Company contact point

If you have any questions about this letter or need more information about Bortezomib 2.5mg/ml Solution for Injection, please contact Thornton & Ross Ltd, Linthwaite, Huddersfield, HD7 5QH, UK or Telephone +44 (0) 1484 848164 or e-mail thorntonross@medinformation.co.uk.

Signed: 

Date: 02/09/2021

David Williams
CEO Medical Affairs
Thornton & Ross Limited