16th January 2012

Dear Healthcare Professional,

The correct administration of VELCADE (bortezomib) is via the intravenous route.

The purpose of this communication is to remind you that the correct procedure for administering VELCADE (bortezomib) 3.5 mg powder for solution for injection is via the intravenous route and to recommend some measures to reduce the risk of incorrect administration.

This communication has been agreed with the European Medicines Agency and the Irish Medicines Board.

AUTHORISED ROUTE OF ADMINISTRATION

The **only** authorised route of administration for VELCADE is intravenous injection.
VELCADE **must not** be administered by any other route.

RECOMMENDED PRECAUTIONARY MEASURES

In order to reduce administration route errors, the following specific precautionary measures should be considered:

- When possible, use different connectors for medicinal products to be administered via the intrathecal or intravenous route.
- When possible, administer intrathecal chemotherapy at a different time to any other parenteral chemotherapy.
- Clearly label syringes with the name of medicinal product and route of administration to be used.
- Ensure procedures are in place to enforce double reading of syringe labelling before administration.
- Intravenous and intrathecal injections should be handled only by trained healthcare professionals.
- Train and inform healthcare professionals involved in administration and/or management of oncology chemotherapy on dangers of intrathecal administration of VELCADE and the above risk minimisation measures.

FURTHER INFORMATION ON THE SAFETY CONCERN

VELCADE is a cytotoxic agent currently approved via intravenous injection as a single agent or in combination with oral melphalan and oral prednisone for the treatment of patients with multiple myeloma.

Since the first approval of VELCADE in the United States on 13 May 2003, three cases of inadvertent intrathecal administration with fatal outcome have been reported worldwide. Each case can be considered accidental and occurred when an intrathecal oncology chemotherapy was scheduled at the same time as the VELCADE intravenous administration.

PREPARATION AND ADMINISTRATION INSTRUCTIONS

VELCADE must be reconstituted by a healthcare professional.

Before reconstitution, check the vial label for the name and the strength of the medicinal product. After reconstitution of the powder with sterile 9 mg/ml (0.9%) sodium chloride solution, check the dose in the syringe according to the posology, and inject the solution as a 3-5 second bolus injection through an intravenous catheter. Flush the catheter with sterile 9 mg/ml (0.9%) sodium chloride solution.

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Please refer to the "Information for Medical or Healthcare Professionals" section of the Package Leaflet and the Summary of Product Characteristics (SmPC) for complete instructions on the reconstitution and administration of VELCADE. The SmPC and the Package Leaflet are available from Medical Information, Janssen-Cilag Ltd, 50 -100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK, 1800 709122 or medinfo@janssen-cilag.co.uk, or via the internet at www.medicines.ie.

CALL FOR REPORTING

Healthcare professionals should report any suspected adverse reactions associated with the use of VELCADE to the Irish Medicines Board, online at www.imb.ie, by e-mail at imbpharmacovigilance@imb.ie, telephone 353-1-6764971, fax 353-1-6762517 or by post at 'FREEPOST', Pharmacovigilance Section, Human Products Monitoring Department, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2

Suspected adverse reactions should also be reported to Janssen-Cilag on tel: +44(0)1494 567447, fax: +44(0)1494 567799 or by e-mail at dsafety@its.jnj.com.

Further Information

If you have further questions, please do not hesitate to contact Adrian Fenlon, Janssen Ireland on 087 7988442 or the Medical Information department on 1800 709122.

Yours faithfully,

Dr Michelle De Brun
Head of Medical Affairs
Janssen Ireland

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