Summary Public Assessment Report

Generics

Bortezomib Glenmark 1 mg and 3.5 mg powder for solution for injection

(bortezomib)

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Active substance: bortezomib

This is a summary of the public assessment report (PAR) for Bortezomib Glenmark. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use this medicine.

For practical information about using this medicine, patients should read the package leaflet or contact their doctor or pharmacist.

What is Bortezomib Glenmark and what is it used for?
Bortezomib Glenmark is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Velcade.

Bortezomib Glenmark is used for the treatment of multiple myeloma (a cancer of the bone marrow) in patients older than 18 years:

- alone or together with the medicines pegylated liposomal doxorubicin or dexamethasone, for patients whose disease is worsening (progressive) after receiving at least one prior treatment and for whom blood stem cell transplantation was not successful or is unsuitable.
- in combination with the medicines melphalan and prednisone, for patients whose disease has not been previously treated and are unsuitable for high-dose chemotherapy with blood stem cell transplantation.
- in combination with the medicines dexamethasone or dexamethasone together with thalidomide, for patients whose disease has not been previously treated and before receiving high-dose chemotherapy with blood stem cell transplantation (induction treatment).

Bortezomib Glenmark is used for the treatment of mantle cell lymphoma (a type of cancer affecting the lymph nodes) in patients 18 years or older in combination with the medicines rituximab, cyclophosphamide, doxorubicin and prednisone, for patients whose disease has not been previously treated and for whom blood stem cell transplantation is unsuitable.

How does this medicine work?
This medicine contains the active substance bortezomib, a so-called 'proteasome inhibitor'. Proteasomes play an important role in controlling cell function and growth. By interfering with their function, bortezomib can kill cancer cells.

How is this medicine used?
The pharmaceutical form of Bortezomib Glenmark is powder for solution for injection. It is administered into a vein or under the skin. The medicine can only be obtained with a prescription.

The dose of Bortezomib Glenmark is calculated according to height and weight (body surface area). The usual starting dose of this medicine is 1.3 mg/m^2 body surface area twice a week. The doctor may change the dose and total number of treatment cycles, depending on the response of the patient to the treatment on the occurrence of certain side effects and on underlying conditions (e.g. liver problems).

This medicine is administered by a health care professional experienced in the use of cytotoxic medicines. The powder of this medicine has to be dissolved before administration. The resulting solution is then either injected into a vein or under the skin. Injection into a vein is rapid, taking 3 to 5 seconds. Injection under the skin is in either the thighs or the abdomen.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
The company provided data from the published literature on bortezomib. No additional studies were needed as Bortezomib Glenmark is a generic medicine that is given by intravenous injection and contains the same active substance as the reference medicine, Velcade.

What are the possible side effects of this medicine?
Because Bortezomib Glenmark is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Velcade, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Bortezomib Glenmark, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about this medicine
In the Netherlands, the marketing authorisation for Bortezomib Glenmark 1 mg and 3.5 mg powder for solution for injection was granted on 12 October 2015.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with Bortezomib Glenmark, read the package leaflet (http://mri.medagencies.org/Human/Product/Details/44408;http://mri.medagencies.org/Human/Product/Details/44403) or contact your doctor or pharmacist.

This summary was last updated in March 2016.