Summary Public Assessment Report

Generics

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

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Bortezomib Teva

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

This is a summary of the public assessment report (PAR) for Bortezomib Teva. It explains how Bortezomib Teva 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 Bortezomib Teva.

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

What is Bortezomib Teva and what is it used for?

Bortezomib Teva is a 'generic medicine'. This means that Bortezomib Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called Velcade 1 mg and 3.5 mg powder for solution for injection
Bortezomib Teva is used in 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 Teva is also 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 Bortezomib Teva work?

Bortezomib Teva 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 Bortezomib Teva used?

The pharmaceutical form of Bortezomib Teva is powder for solution for injection. Bortezomib Teva 1 mg is for intravenous (into a vein) use only. Bortezomib Teva 3.5 mg is for intravenous (into a vein) or subcutaneous (under the skin) use.

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

The medicine can only be obtained with a prescription.

What benefits of Bortezomib Teva have been shown in studies?
No additional studies were needed as Bortezomib Teva is a generic medicine that is given by intravenous injection or subcutaneous injection and contains the same active substance as the reference medicine Velcade.

What are the possible side effects of Bortezomib Teva?
Because Bortezomib Teva 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 restrictions, see the package leaflet.

Why is Bortezomib Teva approved?
It was concluded that, in accordance with EU requirements, Bortezomib Teva has been shown to be comparable to Velcade. Therefore, the member states involved in the procedure decided that, as for the reference product 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 Bortezomib Teva?
A risk management plan has been developed to ensure that Bortezomib Teva 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 Teva, 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.

In order to minimize the risk of medication and dispensing errors, educational materials for healthcare professionals are being provided by the marketing authorisation holder.

Other information about Bortezomib Teva

The marketing authorisation for Bortezomib Teva was granted on 29th June 2015.

The full PAR and the package leaflet for Bortezomib Teva can be found on the website http://mri.medagencies.org/Human/. For more information about treatment with Bortezomib Teva, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in August 2015.