Summary Public Assessment Report

Generics

Bendamustine Actavis
(Bendamustine hydrochloride)

DK/H/2378/001/DC

Date: 22-05-2015

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Bendamustine Actavis

Bendamustine hydrochloride, 2.5 mg/ml powder for concentrate for solution for infusion

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

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

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

Bendamustine Actavis is used alone (monotherapy) or in combination with other medicines for the treatment of the following forms of cancer:
- chronic lymphocytic leukaemia in cases where fludarabine combination chemotherapy is not appropriate for you.
- non-Hodgkin's lymphomas, which had not, or only shortly, responded to prior rituximab treatment.
- Multiple myeloma in cases where highdose chemotherapy with autologous stem cell transplantation, thalidomide or bortezomib containing therapy is not appropriate for you.

How does Bendamustine Actavis work?
Bendamustine Actavis is used in the treatment of certain types of cancer (cytotoxic medicine).

How is Bendamustine Actavis used?
The pharmaceutical form of Bendamustine Actavis is powder for concentrate for solution for infusion and the route of administration is For intravenous use as infusion.

Please read section 3 of the package leaflet 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 Bendamustine Actavis have been shown in studies?
No additional studies were needed as Bendamustine Actavis is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Levact.

What are the possible side effects of Bendamustine Actavis?
Because Bendamustine Actavis 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 Bendamustine Actavis approved?
It was concluded that, in accordance with EU requirements, Bendamustine Actavis has been shown to have comparable quality and to be comparable to Levact. Therefore, the member

states involved in the procedure concluded that, as for Levact, 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 Bendamustine Actavis?

A risk management plan has been developed to ensure that Bendamustine Actavis 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 Bendamustine Actavis, 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 Bendamustine Actavis

The marketing authorisation for Bendamustine Actavis was granted on March 17th 2015.

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

This summary was last updated in 05-2015