

# **Summary Public Assessment Report**

## **Generics**

**Bendamustine Hydrochloride Stada  
(Bendamustine hydrochloride)**

**DK/H/2413/001/DC**

**Date: 06-07-2015**

## Summary Public Assessment Report

### Bendamustine Hydrochloride Stada

#### **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 Hydrochloride Stada . It explains how Bendamustine Hydrochloride Stada 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 Hydrochloride Stada .

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

#### **What is Bendamustine Hydrochloride Stada and what is it used for?**

Bendamustine Hydrochloride Stada is a 'generic medicine'. This means that Bendamustine Hydrochloride Stada is similar to a 'reference medicine' already authorised in the European Union (EU) called Levact.

Bendamustine Hydrochloride Stada 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 Hydrochloride Stada work?**

Bendamustine Hydrochloride Stada is used in the treatment of certain types of cancer (cytotoxic medicine).

#### **How is Bendamustine Hydrochloride Stada used?**

The pharmaceutical form of Bendamustine Hydrochloride Stada 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 Hydrochloride Stada have been shown in studies?**

No additional studies were needed as Bendamustine Hydrochloride Stada 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 Hydrochloride Stada ?**

Because Bendamustine Hydrochloride Stada 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 side effects and restrictions, see the package leaflet.

### **Why is Bendamustine Hydrochloride Stada approved?**

It was concluded that, in accordance with EU requirements, Bendamustine Hydrochloride Stada 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 Hydrochloride Stada ?**

A risk management plan has been developed to ensure that Bendamustine Hydrochloride Stada 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 Hydrochloride Stada , 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 Hydrochloride Stada**

The marketing authorisation for Bendamustine Hydrochloride Stada was granted on 4<sup>th</sup> June, 2015.

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

This summary was last updated in 07-2015