Public Assessment Report

Update

Bendamustin Actavis
(Bendamustine hydrochloride)

DK/H/2378/001/E/002

Date: 08-10-2018

This module reflects the procedural steps and scientific information after the finalisation of the initial procedure.

Scope	Procedure number	Product Information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached
Repeat use procedure with EE, SE, SI and UK	DK/H/2378/001/E/001	No	21-08-2015	19-11-2015	Approval	Y, Annex 1
Repeat use procedure with HR, HU and NL	DK/H/2378/001/E/002	No	08-08-2018	07-10-2018	Approval	Y, Annex 2

ANNEX 1 – Repeat use procedure (DK/H/2378/001/E/001)

The repeat use procedure started on August 21, 2015. There was no discussion in the CMD(h). Agreement between member states was reached during a written procedure. The concerned member States (EE, SE, SI, UK), on the basis of the data submitted, considered that a marketing authorization could be granted.

The repeat use procedure was finalised on November 19, 2015

Periodic Safety Update Report (PSUR)
With regard to PSUR submission, the MAH should take the following into account:

- PSURs shall be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal. Marketing authorisation holders shall continuously check the European medicines web-portal for the DLP and frequency of submission of the next PSUR.
- For medicinal products authorized under the legal basis of Article 10(1) or Article 10a of Directive 2001/83/EC, no routine PSURs need to be submitted, unless otherwise specified in the EURD list.
- For medicinal products that do not fall within the categories waived of the obligation to submit routine PSURs by the revised pharmacovigilance legislation, the MAH should follow the DLP according to the EURD list.

Common renewal date
The common renewal date is February 18th, 2020 based on the approval date of the initial DC procedure.

Additional risk minimisation measures
There are no conditions pursuant to Article 21a or 22 of Directive 2001/83/EC.

List of commitments
The following post-approval commitments have been made during the repeat use procedure:

1. The package leaflet will be updated in line with day 50 comments from SE in the repeat use procedure DK/H/2378/001/E/001. These editorial updates will be proposed during the next regulatory opportunity, i.e. in conjunction with another variation affecting the Product information of classification C.

ANNEX 2 – Repeat use procedure (DK/H/2378/001/E/002)

The repeat use procedure started on August 8, 2018. There was no discussion in the CMD(h). Agreement between member states was reached during a written procedure. The concerned member States (HR, HU and NL), on the basis of the data submitted, considered that a marketing authorization could be granted.

The repeat use procedure was finalised on October 7, 2018.

Periodic Safety Update Report (PSUR)
With regard to PSUR submission, the MAH should take the following into account:

- PSURs shall be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal. Marketing authorisation holders shall continuously check the European medicines web-portal for the DLP and frequency of submission of the next PSUR.
- For medicinal products authorized under the legal basis of Article 10(1) or Article 10a of Directive 2001/83/EC, no routine PSURs need to be submitted, unless otherwise specified in the EURD list.
- For medicinal products that do not fall within the categories waived of the obligation to submit routine PSURs by the revised pharmacovigilance legislation, the MAH should follow the DLP according to the EURD list.

Common renewal date
The common renewal date is February 18th, 2020 based on the approval date of the initial DC procedure.

Additional risk minimisation measures
There are no conditions pursuant to Article 21a or 22 of Directive 2001/83/EC.

List of commitments
The following post-approval commitments have been made during the repeat use procedure:

1. The current RMP will be brought in line with the GVP module V revision 2 and the safety specifications will be updated in line with the reference product via appropriate variation procedure within 3 months after finalization of the RUP.
2. The current SmPC and PL will be brought in line with the approved Product Information of the originator product Levact 2.5 mg/ml powder for concentrate for solution for infusion via appropriate variation procedure within 3 months after finalization of the RUP.