



## Daurismo

### Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
IB/0007	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	05/07/2022		SmPC and PL	
PSUSA/10859 /202111	Periodic Safety Update EU Single assessment - glasdegib	10/06/2022	n/a		PRAC Recommendation - maintenance

<sup>1</sup> Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

<sup>2</sup> A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



PSUSA/10859 /202105	Periodic Safety Update EU Single assessment - glasdegib	02/12/2021	n/a		PRAC Recommendation - maintenance
IB/0004/G	This was an application for a group of variations.  B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation A.6 - Administrative change - Change in ATC Code/ATC Vet Code	10/06/2021	28/03/2022	SmPC	B.II.b.4.z - Change from a single batch size to a batch size range of the finished product from 23.1 kg to 18.5 kg. A.6 - To change the ATC Code of glasdegib from L01XX63 to L01XJ03. The MAH has taken this opportunity to update the Product Information Annexes III A & III B with minor administrative updates.
PSUSA/10859 /202011	Periodic Safety Update EU Single assessment - glasdegib	10/06/2021	n/a		PRAC Recommendation - maintenance
IB/0003/G	This was an application for a group of variations.  B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) B.II.f.1.e - Stability of FP - Change to an approved stability protocol	15/04/2021	28/03/2022	SmPC and PL	
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/11/2020	28/03/2022	PL	