Miglustat Gen.Orph

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB /	C.I.2 Change(s) in the Summary of Product	24/06/2025		SmPC and PL	To update Section 4.4 of the SmPC and Section 2 of

[1] 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.
[2] 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.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000279222	Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2.a - To update Section 4.4 of the SmPC and Section 2 of the PL with information regarding the fact that cases of Crohn's disease have been reported post-marketing. The change follows assessment of the same change to the reference product Zavesca.				the PL with information regarding the fact that cases of Crohn's disease have been reported post-marketing. The change follows assessment of the same change to the reference product Zavesca.
Article 61(3) / EMA/N/0000240915	- Notification acc. Article 61(3) - Update of the package leaflet with revised details of a local representative.	14/01/2025		PL	
Variation type IA / EMA/VR/0000235965	This was an application for a group of variations. B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.4 Deletion of certificates (in case multiple certificates exist per material) - Accepted B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active	04/11/2024	N/A		

	substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.3 Updated certificate from an already approved manufacturer - Accepted B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.3 Updated certificate from an already approved manufacturer - Accepted B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.2 New certificate for a starting material/reagent/ intermediate/or excipient from a new or an already approved manufacturer - Accepted				
Article 61(3) / EMA/N/0000168293	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives.	20/02/2024	25/04/2024	PL	