Miglustat Dipharma

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	16/06/2025		SmPC and PL	To update section 4.4 of the SmPC in order to add

[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/0000263310	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 To update section 4.4 of the SmPC in order to add information regarding cases of Crohn's disease; a warning concerning Crohn’s disease cases reported in Niemann–Pick type C (NP-C) disease patients treated with miglustat in post-marketing setting has been reported. In addition, PRAC considered that the PI should be updated in order to better highlight the risk of reduced growth in the paediatric population. In addition the MAH has taken this opportunity to make minor corrections in the description of the packaging and of the capsules.				information regarding cases of Crohn's disease; a warning concerning Crohn’s disease cases reported in Niemann–Pick type C (NP-C) disease patients treated with miglustat in post-marketing setting has been reported. In addition, PRAC considered that the PI should be updated in order to better highlight the risk of reduced growth in the paediatric population. In addition the MAH has taken this opportunity to make minor corrections in the description of the packaging and of the capsules.