EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Nimvastid

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
Article 61(3) /	- Notification acc. Article 61(3) - Accepted	15/07/2025		PL	

[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/N/0000284684	Update of the product information to align the ADRs listed in sections '4. Possible side effects' of the package leaflet with section 4.8 of the SmPC.				
Variation type IB / EMA/VR/0000253876	C.I.2 Change(s) in the Summary of Product 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 (IB) - To update section 4.8 of the SmPC and section 4 of the Package Leaflet to add the adverse reaction Pleurothotonus (Pisa syndrome) with a frequency 'not known" under the Soc Nervous system disorders, following approval of the same change in the reference product. Furthermore, the Marketing Authorisation Holder has taken the opportunity to update the list of local representatives and implement editorial changes in DA, CS, EL, and HU to correct typographical errors and align with the reference product annexes.	26/03/2025		SmPC and PL	To update section 4.8 of the SmPC and section 4 of the Package Leaflet to add the adverse reaction Pleurothotonus (Pisa syndrome) with a frequency 'not known" under the Soc Nervous system disorders, following approval of the same change in the reference product.
Variation type IA_IN / EMA/VR/0000177024	B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active	08/05/2024	N/A		

	substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.a The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer - Accepted				