Nilotinib Accord

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, please 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 HUMAN AND VETERINARY MEDICINAL	07/04/2025		SmPC and PL	To update the sections 4.2, 4.4, 5.2 of the SmPC

[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/0000253330	PRODUCTS - C.I.z Other variation - Accepted To update the sections 4.2, 4.4, 5.2 of the SmPC and section 3 of the PL to carve in the information for administration of nilotinib with apple sauce in patients with swallowing problems in line with the information of reference product. In addition the MAH took this opportunity to correct the number of units per blister.				and section 3 of the PL to carve in the information for administration of nilotinib with apple sauce in patients with swallowing problems in line with the information of reference product. In addition the MAH took this opportunity to correct the number of units per blister.
Variation type IB / EMA/VR/0000256134	This was an application for a group of variations. B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.e Minor change to the restricted part of an Active Substance Master File - Accepted B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.a Up to 10-fold increase compared to the originally approved batch size - Accepted	01/04/2025	N/A		
Variation type IA / EMA/VR/0000261776	B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.a Up to 10-fold compared to the originally approved batch size - Accepted	31/03/2025	N/A		

Variation type IA / EMA/VR/0000261828	B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.a Up to 10-fold compared to the originally approved batch size - Accepted	31/03/2025	N/A		