Usrenty

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	13/02/2026		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/0000326583	Update of the package leaflet with revised contact details of local representatives.				
Variation type IA / EMA/VR/0000324457	This was an application for a group of variations. B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.a Tightening of specification limits - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.a Minor changes to an approved test procedure - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.a Minor changes to an approved test procedure - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.a Minor changes to an approved test procedure - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the	05/02/2026			

	finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.b Addition of a new test(s) and limits - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.b Addition of a new test(s) and limits - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.b Addition of a new test(s) and limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted				

	B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active				

	substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.III.2.a Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.a.2 Excipient/active substance starting material - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted				