



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Lamzede

### 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 <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
Variation type IB /	C.I HUMAN AND VETERINARY MEDICINAL	02/03/2026		SmPC and PL	

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



EMA/VR/0000310242	<p>PRODUCTS - C.I.z Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc.</p> <p>Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon. - Accepted</p> <p>C.I.z – to update section 4.8 of the SmPC by adding three IRR events (apathy, pallor and hypotonia) recommendation following the 7th Annual Reassessment - procedure no EMA/S/0000257415. Consequently, section 4 of the PL has been updated. In addition, the MAH took the opportunity to update the list of local representatives in BG, HU, PL and implement the QRD version 10.4 (Windsor Framework).</p>				
Variation type IB / EMA/VR/0000279869	<p>This was an application for a group of variations.</p> <p>B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted</p> <p>B.II.b.3 Change in the manufacturing process of the finished product, including an</p>	25/07/2025			

	intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted				
Annual reassessment - H / EMA/S/0000257415		24/07/2025			
Variation type IB / EMA/VR/0000272597	<p>This was an application for a group of variations.</p> <p>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.h Addition or replacement (excluding biological or immunological substance) of a specification parameter with its corresponding test method as a result of a safety or quality issue - Accepted</p> <p>B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted</p> <p>B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted</p>	12/06/2025			

<p>Variation type IA / EMA/VR/0000247783</p>	<p>This was an application for a group of variations.</p> <p>A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted</p> <p>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</p>	<p>05/02/2025</p>			
<p>PSUR / EMA/PSUR/0000282224</p>					<p>Maintenance</p>