Zutectra

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 II /	B.II.d.1 Change in the specification	18/09/2025		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/0000284874	parameters and/or limits of the finished product - B.II.d.1.e Change outside the approved specifications limits range - Accepted			Labelling and PL	
Variation type IA_IN / EMA/VR/0000290372	B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - B.V.a.1.d Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product - Accepted	06/08/2025	N/A		
Variation type IA_IN / EMA/VR/0000264631	This was an application for a group of variations. B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - B.V.a.1.d Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product - Accepted B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - B.V.a.1.d Inclusion of an updated/amended	09/04/2025	N/A		

	Plasma Master File when changes do not affect the properties of the finished product - Accepted				
Variation type IA_IN / EMA/VR/0000258494	B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - B.V.a.1.d Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product - Accepted	25/03/2025	N/A		