Retacrit

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 IB /	C.I HUMAN AND VETERINARY MEDICINAL	26/09/2025		SmPC and 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/VR/0000292973	PRODUCTS - C.I.z Implementation of an agreed wording, no new data submitted - Accepted To update sections 2, 4.4 and 6.1 of the SmPC to the wording of the excipients guideline on Polysorbate 20. The Package leaflet is updated accordingly				To update sections 2, 4.4 and 6.1 of the SmPC to the wording of the excipients guideline on Polysorbate 20. The Package leaflet is updated accordingly
Variation type IB / EMA/VR/0000290652	This was an application for a group of variations. 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.z Other changes - 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.z Other changes - Accepted	29/08/2025	N/A		
Variation type IB / EMA/VR/0000256598	B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.c Implementation of a change for a biological/immunological medicinal product - Accepted	02/05/2025	N/A		

Article 61(3) / EMA/N/0000263961	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives and to delete 'United Kingdom (Northern Ireland)' from the list of local representatives in line with the QRD template v10.4.	16/04/2025		PL	