Briumvi

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 /	C.I HUMAN AND VETERINARY MEDICINAL	04/09/2025		SmPC and PL	Update of section 4.2 of the SmPC in order to align

[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/0000279394	PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 4.2 of the SmPC in order to align the text with section 4.4 regarding antihistamine premedication based on literature. PL is updated accordingly. In addition, the MAH took the opportunity to correct an error in table 3 of the SmPC in section 5.1 and another one in the PL and to update the list of local representatives in the Package Leaflet.				the text with section 4.4 regarding antihistamine premedication based on literature. PL is updated accordingly. In addition, the MAH took the opportunity to correct an error in table 3 of the SmPC in section 5.1 and another one in the PL and to update the list of local representatives in the Package Leaflet. For more information, please refer to the Summary of Product Characteristics.
Variation type IA / EMA/VR/0000287231	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	21/07/2025	N/A		
Variation type II / EMA/VR/0000269324	This was an application for a group of variations. B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of	17/07/2025	N/A		Scope: Please refer to the Recommendations section above Summary: Not applicable

	the test methods performed at the site is a biological/immunological method - 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.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.j Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of				

	the approved dossier - B.I.a.1.a The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer - Accepted				
PSUR / EMA/PSUR/0000257796	- -				Maintenance