



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Brinsupri

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 /	Outcome:	15/09/2026		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/0000366005	This was an application for a group of variations. Q.II.f.1 Change in the shelf life or storage - Q.II.f.1.z Other variation - Accepted Q.II.f.1 Change in the shelf life or storage - Q.II.f.1.e Change to an approved stability protocol of the finished product - Accepted Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.5 Extension of the shelf life of the finished product based on extrapolation of stability data in accordance with relevant stability guidelines - Accepted Q.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Q.II.b.3.e) Change in the holding time and/or storage conditions of an intermediate or bulk product used in the manufacture of the finished product - Accepted				
Variation type IB / EMA/VR/0000348740	Outcome: This was an application for a group of variations. Q.I.b.1 Change in the specification attribute and/or acceptance criteria of an active substance, starting material/reagent/intermediate used in the manufacturing process of the active	18/06/2026			

	substance - Q.I.b.1.h) Change outside of the specification acceptance criteria for starting material/reagent/intermediate - Accepted Q.I.b.1 Change in the specification attribute and/or acceptance criteria of an active substance, starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.1.d) Deletion of a non-significant or an obsolete specification attribute - Accepted Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.a) Minor change in the manufacturing process - Accepted Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.a) Minor change in the manufacturing process - Accepted E.4 Change in the name and/or address of the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank, manufacturing site for an active substance, intermediate or finished product, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or				
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	supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier - E.4.c) The change in the name and/or address does not concern a manufacturer(s) whose activities include batch release of the finished product nor the marketing authorisation holder - Accepted				
Variation type IA / EMA/VR/0000323601	Outcome: This was an application for a group of variations. 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 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	05/02/2026			

	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 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 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.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				
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PSUR / EMA/PSUR/0000344438

EURD: PSUSA/00011170/202602 Active
substance: brensocatib Outcome:
Maintenance

03/09/2026