CRYSVITA

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 /	This was an application for a group of	18/09/2025	21/11/2025	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/0000261369	variations. C.I HUMAN AND VETERINARY MEDICINAL 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 C.I HUMAN AND VETERINARY MEDICINAL 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 A grouped application consisting of: C.I.4: Update of sections 4.4, 4.5, and 4.8 of the SmPC in order to update safety information about Severe Hypercalcaemia in patients with Tertiary Hyperparathyroidism based on data from clinical trials and post-authorisation data sources; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted. In addition, the MAH took the opportunity (1) to improve the existing guidance in section 4.2 based on the accumulated clinical experience, (2) to introduce editorial changes to the PI, (3) to bring the PI in line with the latest QRD template, current guidelines, and PEI requests. C.I.4: Update			Labelling and PL	

	of section 4.8 of the SmPC in order to add urticaria to the list of adverse drug reactions (ADRs) with frequency common based on data from clinical trials and post-authorisation data sources; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted.				
Variation type II / EMA/VR/0000280187	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	04/09/2025	21/11/2025		
Variation type II / EMA/VR/0000246754	C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.b	10/04/2025	21/11/2025	SmPC and PL	

	Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH - Accepted Update of section 4.6 of the SmPC in order to add a statement on how long contraception should be continued after burosumab treatment has been discontinued, as requested in procedure PSUSA/00010669/202402. The Package Leaflet is updated accordingly.				
PSUR / EMA/PSUR/0000274414	- -				