Opsumit

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.3 Change(s) in the summary of product	23/04/2026		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/0000324354	characteristics, labelling or package leaflet intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Article 45 or 46 of Regulation (EC) No 1901/2006, or the outcome of a PRAC signal recommendation, or to adapt to a joint recommendation of EU competent authorities (e.g. a Core SmPC, or following the assessment of an Urgent Safety Restriction etc.) - C.3.b) Implementation of the agreed wording that requires additional minor assessment (e.g. translations are not yet agreed upon) - Accepted C.3.b - to update sections 4.8 and 5.1 of the 2.5 of the SmPC with the final data from the completed Japanese paediatric study 67896062PAH3001 assessed with procedure EMA/PAM/0000295189. In addition, the MAH has updated the contact details of the local representative for Belgium, Germany, Luxembourg and the Netherlands in section 6 of the Package Leaflet.				
Variation type IB / EMA/VR/0000313635	B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted	16/12/2025		SmPC and PL	

Variation type IB / EMA/VR/0000247082	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z (IB) - To update the Product Information to: - Delete the term "film-coated" from the Opsumit 10mg tablets in Annex IIIA (Labelling). - Correct the frequency of the side effects in children and adolescents, "upper respiratory tract infection" and "gastroenteritis", in section 4 of the Package Leaflet. - Update the information for Slovenia and remove the United Kingdom (Northern Ireland) from the list of local representatives. - Implement minor editorial changes.	04/04/2025		SmPC, Labelling and PL	To update the Product Information to: - Delete the term "film-coated" from the Opsumit 10mg tablets in Annex IIIA (Labelling). - Correct the frequency of the side effects in children and adolescents, "upper respiratory tract infection" and "gastroenteritis", in section 4 of the Package Leaflet. - Update the information for Slovenia and remove the United Kingdom (Northern Ireland) from the list of local representatives.