Janumet

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
Article 61(3) /	- Notification acc. Article 61(3) - Accepted	10/11/2025		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/N/0000309673	Update of the package leaflet with revised contact details of local representatives.				
Variation type IA / EMA/VR/0000289536	B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted	20/08/2025	N/A		
Variation type IB / EMA/VR/0000253633	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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.z Implementation of wording agreed by the competent authority + QRD update - Accepted C.I.3.z To update section 4.4 of the SmPC to implement the signal recommendations from PSUR outcome for the metformin PSUSA/00002001/202404. Section 2 of the Package Leaflet was updated accordingly. In	08/05/2025		SmPC and PL	

	addition, the Product Information was brought in line with the latest QRD template (version 10.4). Minor editorial corrections have also been implemented. The MAH also took the opportunity to update the contact details of the local representatives: - for Janumet: Lithuania, Denmark, Germany, Estonia, Norway, Spain, Iceland, Sweden, Latvia and removal of United Kingdom (Northern Ireland); - for Velmetia: Lithuania, Luxembourg, Spain, Iceland, Sweden, Latvia and removal of United Kingdom (Northern Ireland); - for Efficib: Lithuania, Denmark, Germany, Estonia, Norway, Iceland, Sweden, Latvia and removal of United Kingdom (Northern Ireland); - for Ristfor: Lithuania, Denmark, Germany, Estonia, Norway, Spain, Iceland, Sweden, Latvia and removal of United Kingdom (Northern Ireland).				
Variation type IA / EMA/VR/0000255861	A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted	10/04/2025	N/A		