



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PecFent

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 / EMA/VR/0000339960	Outcome: C. Safety, efficacy, pharmacovigilance changes - C.4 Change(s) in the summary of	18/06/2026		SmPC and PL	Update of sections 4.4, 4.5, 4.8 and 4.9 of the SmPC in order to update safety information based

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).



	product characteristics, labelling or package leaflet due to new quality, preclinical, clinical or pharmacovigilance data. - Accepted Update of sections 4.4, 4.5, 4.8 and 4.9 of the SmPC in order to update safety information based on a signal evaluation report. The Package Leaflet is updated accordingly.				on a signal evaluation report.
Variation type IA_IN / EMA/VR/0000331999	Outcome: C.3 Change(s) in the summary of product 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.a) Implementation of the agreed wording - Accepted	26/02/2026		Labelling and PL	