



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Prometax

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, please 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) -	14/04/2025		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/0000263657	Update of the product information to align the ADRs listed in sections '4 Possible side effects' of the package leaflet with section 4.8 of the SmPC and to introduce an updated image for Prometax transdermal patch (EU/1/98/092/019-042) under 'Where to apply your Prometax transdermal patch' in section '3. How to use Prometax' of the package leaflet. Additionally, the MAH took the opportunity to introduce minor editorial amendments to the package leaflet of some of the translations.				
Variation type IA / EMA/VR/0000262295	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	03/04/2025	N/A		
Variation type IB / EMA/VR/0000248521	This was an application for a group of variations. B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.c Addition of a new specification parameter to the	17/03/2025	N/A		

	specification with its corresponding test method - Accepted B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.a Up to 10-fold increase compared to the originally approved batch size - Accepted				
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