



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Palonosetron Accord

Procedural steps taken and scientific information after the authorisation*

*Due to Agency`s update of its procedure management systems, an additional document, capturing the historical lifecycle may be available in the 'Assessment history' section. For the complete 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 Informatio n affected ³	Summary
Variation type IB /	C.I.2 Change(s) in the Summary of Product	03/04/2024		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/0000171902	<p>Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted</p> <p>To update the package leaflet to align with the user testing assessment for the reference product. The MAH also took this opportunity to correct the SmPC section 4.8 to reflect the QRD recommended reference to appendix V in the reporting of suspected adverse reactions.</p>				
Article 61(3) / EMA/N/0000221332	<p>- Notification acc. Article 61(3) -</p> <p>Update of the package leaflet to include the list of local representatives.</p>	12/07/2024		PL	