



PONVORY

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
IB/0015	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	09/04/2024	n/a		
II/0014	Update of section 4.5 of the SmPC to amend an existing interaction wording for carbamazepine under	08/02/2024		SmPC and PL	Section 4.5 of the SmPC has been amended to inform that no dose adjustment is needed when ponesimod is co-

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).



	<p>the sub-heading "Effect of other medicinal products on ponesimod" based on study 67896153MSC1001. This is a Phase 1, Open-label, Parallel-group Study to Assess the Effect of Steady-state Carbamazepine on the Pharmacokinetics of Ponesimod in Healthy Adult Participants. In addition, the MAH took the opportunity to update the contact details of local representatives in the Package Leaflet.</p> <p>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data</p>				administered with strong CYP3A4 and UGT1A1 inducers. For more information, please refer to the Summary of Product Characteristics.
PSUSA/10940/202303	Periodic Safety Update EU Single assessment - ponesimod	26/10/2023	n/a		PRAC Recommendation - maintenance
IB/0012	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	28/07/2023	n/a		
PSUSA/10940/202209	Periodic Safety Update EU Single assessment - ponesimod	26/04/2023	04/07/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10940/202209.
IB/0010	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	06/02/2023	n/a		
PSUSA/10940/202203	Periodic Safety Update EU Single assessment - ponesimod	27/10/2022	n/a		PRAC Recommendation - maintenance
IB/0008	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a	01/07/2022	n/a		

	re-test period/storage period supported by real time data				
IB/0006	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	30/05/2022	15/03/2023	SmPC	
PSUSA/10940 /202109	Periodic Safety Update EU Single assessment - ponesimod	07/04/2022	n/a		PRAC Recommendation - maintenance
IB/0005	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	15/03/2022	15/03/2023	SmPC, Labelling and PL	
IB/0004/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	28/02/2022	n/a		
IB/0002	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	03/12/2021	n/a		

