



OZAWADE

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
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/11/2023		PL	
IG/1680	B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation	20/10/2023	n/a		

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).



PSUSA/10490 /202209	Periodic Safety Update EU Single assessment - pitolisant	14/04/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10490 /202109	Periodic Safety Update EU Single assessment - pitolisant	05/05/2022	n/a		PRAC Recommendation - maintenance
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/05/2022	16/12/2022	PL	
IB/0003	B.I.d.z - Stability of AS - Other variation	28/04/2022	n/a		
IB/0001	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	06/01/2022	16/12/2022	SmPC, Labelling and PL	