Entacapone Orion

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/0023	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/09/2024		PL	
PSUSA/1223/ 202201	Periodic Safety Update EU Single assessment - entacapone	01/09/2022	n/a		PRAC Recommendation - maintenance

[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).

WS/2202/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.z - Quality change - Active substance - Other variation B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	31/03/2022	n/a		
WS/2096	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	21/10/2021	14/10/2022	SmPC, Labelling and PL	
IG/1277	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	08/10/2020	29/09/2021	Annex II and PL	

WS/1735/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.d.1.b.3 - Stability of AS - Change in the storage conditions - Change in storage conditions of the AS B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	12/03/2020	n/a		
PSUSA/1223/ 201901	Periodic Safety Update EU Single assessment - entacapone	05/09/2019	n/a		PRAC Recommendation - maintenance
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/08/2019	29/09/2021	PL	
IG/0982/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for	26/10/2018	n/a		

	the AS -replacement or addition of a site where batch control/testing takes place				
IG/0888	A.7 - Administrative change - Deletion of manufacturing sites	29/01/2018	n/a		
WS/1064	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	15/12/2016	28/11/2017	SmPC, Annex II, Labelling and PL	
PSUSA/1223/ 201601	Periodic Safety Update EU Single assessment - entacapone	02/09/2016	n/a		PRAC Recommendation - maintenance
R/0011	Renewal of the marketing authorisation.	25/02/2016	08/04/2016		Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Entacapone Orion in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/09/2015	25/01/2016	PL	
IG/0546	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	27/04/2015	n/a		
WS/0665	This was an application for a variation following a worksharing procedure according to Article 20 of	22/01/2015	25/01/2016	SmPC, Labelling and	

	Commission Regulation (EC) No 1234/2008. To update the Product Information as follows: - to include ADR statement - to update the PI to QRD template version 9 - to include an explanation to the PL of the pictogram which is currently only displayed on the carton (all products except Comtan) - to correct the local contact information for Malta in Stalevo PL - to correct the local contact information for Latvia in all PLs except for Comtan and Entacapone Orion - to correct the local contact information for Germany in Comtess and Levodopa/Carbidopa/Entacapone Orion - for Comtan only: to add 'Magnesium stearate' to the list of excipients for the film-coating in the SmPC and PL. Tablet core and Film-coating both contain magnesium stearate - to correct linguistic amendments in Annexes - to amend a mistake in the Annex A (only for Comtan). C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation			PL	
IG/0433/G	This was an application for a group of variations. B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.a - Replacement or addition of a	08/05/2014	n/a		

	manufacturing site for the FP - Secondary packaging site				
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/08/2013	25/01/2016	PL	
WS/0331	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of SmPC sections 4.4 and 4.8 in order to update the safety information by implementing class labelling for the risk of impulse control disorders. C.I.3.z - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Other variation	13/12/2012	14/01/2013	SmPC, Annex II, Labelling and PL	Based on a recent review of the available post-marketing data in relation to the risk of development of impulse control disorders when using medicinal products containing levodopa, dopamine agonists and/or catechol-O-methyltransferase (COMT) inhibitors, the CHMP/PhVWP requested a class labelling to update and harmonise the product information of all products concerned. In response to this request, the product information was updated to reflect behavioural symptoms related to impulse control disorders including compulsive spending or buying, binge eating and compulsive eating. It was clarified that this adverse reaction can occur irrespective of the indication and at normal doses. Furthermore, regular monitoring of patients and a careful review of treatment, if symptoms occur, is recommended. The Package Leaflet was updated in accordance and advice for the patient’s family and carers was provided.
N/0004	The Marketing Authorisation Holder (MAH) took the opportunity to update details of local representatives in Annex IIIB. Furthermore, incorrect package sizes were corrected in section 6 of the Portugese package leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/07/2012	14/01/2013	PL	

N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/03/2012	14/01/2013	PL	
WS/0199	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.III.2.a.1 - Change of specification('s) of a former non Pharmacopoeial substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS	19/01/2012	19/01/2012		
IG/0110	C.I.9.i - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH	04/10/2011	n/a		