Inbrija

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/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/12/2024		PL	
PSUSA/10780 0/202312	Periodic Safety Update EU Single assessment - levodopa	11/07/2024	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).

R/0022	Renewal of the marketing authorisation.	25/04/2024	13/06/2024		
PSUSA/10780 0/202306	Periodic Safety Update EU Single assessment - levodopa	11/01/2024	n/a		PRAC Recommendation - maintenance
IAIN/0021	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	08/12/2023	n/a		
PSUSA/10780 0/202212	Periodic Safety Update EU Single assessment - levodopa	06/07/2023	n/a		PRAC Recommendation - maintenance
IB/0018/G	This was an application for a group of variations. B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation	04/05/2023	n/a		
IB/0017/G	This was an application for a group of variations. 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 B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g.	28/04/2023	14/03/2024	SmPC, Labelling and PL	

	tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes				
PSUSA/107800/202206	Periodic Safety Update EU Single assessment - levodopa	12/01/2023	n/a		PRAC Recommendation - maintenance
IAIN/0015	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	25/11/2022	n/a		
PSUSA/107800/202112	Periodic Safety Update EU Single assessment - levodopa	07/07/2022	n/a		PRAC Recommendation - maintenance
IA/0013/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.f.1.e - Stability of FP - Change to an approved stability protocol	19/04/2022	n/a		
PSUSA/107800/202106	Periodic Safety Update EU Single assessment - levodopa	13/01/2022	n/a		PRAC Recommendation - maintenance
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/12/2021	14/03/2024	PL	
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/11/2021	14/03/2024	PL	

PSUSA/10780 0/202012	Periodic Safety Update EU Single assessment - levodopa	08/07/2021	n/a		PRAC Recommendation - maintenance
IAIN/0007/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	05/07/2021	n/a		
PSUSA/10780 0/202006	Periodic Safety Update EU Single assessment - levodopa	28/01/2021	26/03/2021	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/107800/202006.
IB/0005	B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	18/11/2020	n/a		
IB/0003	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	15/10/2020	n/a		
IA/0004/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release	28/09/2020	n/a		

	arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
PSUSA/107800/201912	Periodic Safety Update EU Single assessment - levodopa	23/07/2020	24/09/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/107800/201912.