Episalvan

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
PSUSA/10446 /202107	Periodic Safety Update EU Single assessment - birch bark extract (centrally authorised product)	10/02/2022	n/a		PRAC Recommendation - maintenance
PSUSA/10446 /202101	Periodic Safety Update EU Single assessment - birch bark extract (centrally authorised product)	02/09/2021	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).

PSUSA/10446 /202007	Periodic Safety Update EU Single assessment - birch bark extract (centrally authorised product)	11/02/2021	n/a		PRAC Recommendation - maintenance
R/0018	Renewal of the marketing authorisation.	23/07/2020	17/09/2020	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Episalvan in the approved indication remains favourable, but recommended that one additional five-year renewal be required based on the following pharmacovigilance grounds: For Episalvan limited safety information is available because of limited exposure due to limited marketing of the medicinal product. As of the DLP, Episalvan has been placed on the market in only one EU country. Episalvan has not yet been commercially launched or placed on the market in any other EU country and thus, no post-authorisation data are currently available. No data on post-authorisation use in special populations were reported as no non-interventional studies, including market research and registries, have been conducted with Episalvan since the granting of the marketing authorization. Therefore, based upon the limited safety profile of Episalvan, the CHMP concluded that the MAH should submit one additional renewal application in 5 years time.
PSUSA/10446 /202001	Periodic Safety Update EU Single assessment - birch bark extract (centrally authorised product)	04/09/2020	n/a		PRAC Recommendation - maintenance
PSUSA/10446 /201907	Periodic Safety Update EU Single assessment - birch bark extract (centrally authorised product)	13/02/2020	n/a		PRAC Recommendation - maintenance
IAIN/0016/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH	05/02/2020	17/09/2020	SmPC, Annex II, Labelling and PL	

	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release				
IB/0014/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.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information B.II.e.7.b - Change in supplier of packaging	17/10/2019	n/a		

	components or devices (when mentioned in the dossier) - Replacement or addition of a supplier				
PSUSA/10446 /201901	Periodic Safety Update EU Single assessment - birch bark extract (centrally authorised product)	11/07/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10446 /201807	Periodic Safety Update EU Single assessment - birch bark extract (centrally authorised product)	14/02/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10446 /201801	Periodic Safety Update EU Single assessment - birch bark extract (centrally authorised product)	12/07/2018	n/a		PRAC Recommendation - maintenance
II/0010	B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	05/07/2018	n/a		
IB/0009	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)	30/05/2018	03/05/2019	SmPC	
IB/0011	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	28/05/2018	n/a		
IB/0008	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	17/05/2018	n/a		
PSUSA/10446	Periodic Safety Update EU Single assessment - birch	08/02/2018	n/a		PRAC Recommendation - maintenance

/201707	bark extract (centrally authorised product)				
IAIN/0005/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	09/10/2017	05/02/2018	SmPC, Annex II, Labelling and PL	
PSUSA/10446 /201701	Periodic Safety Update EU Single assessment - birch bark extract (centrally authorised product)	01/09/2017	n/a		PRAC Recommendation - maintenance
IA/0003/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	15/03/2017	n/a		
IA/0002/G	This was an application for a group of variations.	16/02/2017	05/02/2018	SmPC	

	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.6 - Administrative change - Change in ATC Code/ATC Vet Code B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
PSUSA/10446 /201607	Periodic Safety Update EU Single assessment - birch bark extract (centrally authorised product)	09/02/2017	n/a		PRAC Recommendation - maintenance