Chenodeoxycholic acid Leadiant

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
R/0018	Renewal of the marketing authorisation.	14/10/2021	09/12/2021	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 Chenodeoxycholic acid Leadiant in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

[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).

S/0017	4th annual re-assessment.	14/10/2021	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation under exceptional circumstances of Chenodeoxycholic acid Leadiant should be maintained.
PSUSA/10590 /202010	Periodic Safety Update EU Single assessment - chenodeoxycholic acid (inborn error in primary bile acid synthesis, xanthomatosi - centrally authorised products only)	06/05/2021	n/a		PRAC Recommendation - maintenance
IB/0015/G	This was an application for a group of variations. 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 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 B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	06/01/2021	n/a		
S/0014	3rd annual re-assessment	23/07/2020	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the

					medicinal product, concluded that marketing authorisation under exceptional circumstances of Chenodeoxycholic acid Leadiant should be maintained.
PSUSA/10590 /201910	Periodic Safety Update EU Single assessment - chenodeoxycholic acid (inborn error in primary bile acid synthesis, xanthomatosi - centrally authorised products only)	17/04/2020	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	08/01/2020	17/12/2020	SmPC and Annex II	
PSUSA/10590 /201904	Periodic Safety Update EU Single assessment - chenodeoxycholic acid (inborn error in primary bile acid synthesis, xanthomatosi - centrally authorised products only)	31/10/2019	n/a		PRAC Recommendation - maintenance
S/0010	2nd annual re-assessment.	17/10/2019	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of Chenodeoxycholic acid Leadiant should be maintained.
PSUSA/10590 /201810	Periodic Safety Update EU Single assessment - chenodeoxycholic acid (inborn error in primary bile acid synthesis, xanthomatosi - centrally authorised products only)	16/05/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10590 /201804	Periodic Safety Update EU Single assessment - chenodeoxycholic acid (inborn error in primary bile acid synthesis, xanthomatosi - centrally authorised	31/10/2018	n/a		PRAC Recommendation - maintenance

	products only)				
IA/0008/G	This was an application for a group of variations. B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates	29/08/2018	n/a		

	exist per material)				
S/0006	Annual re-assessment.	26/07/2018	n/a		
PSUSA/10590 /201710	Periodic Safety Update EU Single assessment - chenodeoxycholic acid (inborn error in primary bile acid synthesis, xanthomatosi - centrally authorised products only)	17/05/2018	n/a		PRAC Recommendation - maintenance
IB/0004	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)	28/09/2017	31/05/2018	SmPC	
IB/0003/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	04/07/2017	31/05/2018	Annex II and PL	
T/0001	Transfer of Marketing Authorisation	12/05/2017	31/05/2017	SmPC, Labelling and PL	
IB/0002/G	This was an application for a group of variations. A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer	12/05/2017	31/05/2017	SmPC, Annex II, Labelling and PL	

	responsible for batch release B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation				