



LysaKare

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/0016	Renewal of the marketing authorisation.	22/02/2024	25/04/2024	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 LysaKare in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. Minor changes are implemented in the PI in line with the latest QRD template.

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).



					Relevant statements have been added in sections 4.2 for the Elderly and Hepatic impairment and 4.6 for women of childbearing potential, contraception, and pregnancy of the SmPC. Sections of Warning and precautions and Possibleside effects of the PL have also been updated.
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/02/2024	25/04/2024	PL	
PSUSA/10786 /202307	Periodic Safety Update EU Single assessment - l-lysine hydrochloride / l-arginine hydrochloride	08/02/2024	n/a		PRAC Recommendation - maintenance
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/09/2023	16/02/2024	PL	
IAIN/0013	A.1 - Administrative change - Change in the name and/or address of the MAH	13/02/2023	16/02/2024	SmPC, Labelling and PL	
PSUSA/10786 /202207	Periodic Safety Update EU Single assessment - l-lysine hydrochloride / l-arginine hydrochloride	09/02/2023	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	25/11/2022	n/a		
PSUSA/10786 /202201	Periodic Safety Update EU Single assessment - l-lysine hydrochloride / l-arginine hydrochloride	01/09/2022	n/a		PRAC Recommendation - maintenance
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/06/2022	16/02/2024	PL	

PSUSA/10786 /202107	Periodic Safety Update EU Single assessment - l-lysine hydrochloride / l-arginine hydrochloride	10/02/2022	n/a		PRAC Recommendation - maintenance
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/10/2021	16/02/2024	PL	
PSUSA/10786 /202101	Periodic Safety Update EU Single assessment - l-lysine hydrochloride / l-arginine hydrochloride	02/09/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10786 /202007	Periodic Safety Update EU Single assessment - l-lysine hydrochloride / l-arginine hydrochloride	11/02/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10786 /202001	Periodic Safety Update EU Single assessment - l-lysine hydrochloride / l-arginine hydrochloride	03/09/2020	n/a		PRAC Recommendation - maintenance
IB/0003	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	27/03/2020	n/a		
IA/0002	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	17/01/2020	n/a		
IA/0001	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	17/12/2019	n/a		