Xenleta

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/0010	Renewal of the marketing authorisation.	30/01/2025	04/04/2025	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 Xenleta 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).

PSUSA/10872 /202408	Periodic Safety Update EU Single assessment - lefamulin	13/03/2025	n/a		PRAC Recommendation - maintenance
PSUSA/10872 /202308	Periodic Safety Update EU Single assessment - lefamulin	07/03/2024	n/a		PRAC Recommendation - maintenance
PSUSA/10872 /202208	Periodic Safety Update EU Single assessment - lefamulin	16/03/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10872 /202202	Periodic Safety Update EU Single assessment - lefamulin	29/09/2022	n/a		PRAC Recommendation - maintenance
PSUSA/10872 /202108	Periodic Safety Update EU Single assessment - lefamulin	10/03/2022	n/a		PRAC Recommendation - maintenance
PSUSA/10872 /202102	Periodic Safety Update EU Single assessment - lefamulin	30/09/2021	n/a		PRAC Recommendation - maintenance
IB/0005	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)	23/06/2021	08/07/2022	SmPC	To change the shelf life of the finished product form 3 to 4 years in section 6.3 of the Summary of Product Characteristics.
PSUSA/10872 /202008	Periodic Safety Update EU Single assessment - lefamulin	11/03/2021	n/a		PRAC Recommendation - maintenance
IB/0003	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/02/2021	n/a		
IA/0001/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	28/10/2020	n/a		

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