Chenodeoxycholic acid Leadiant

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Marketing Authorisation	Outcome:	30/07/2026	12/08/2026	SmPC,	

[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).

Transfer - H / EMA/T/0000362275	Transfer of marketing authorisation from Leadiant GmbH to Leadiant Biosciences Ireland Limited			Labelling and PL	
Annual reassessment - H / EMA/S/0000340415	Outcome: 9th annual re-assessment	23/07/2026			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 Orphacol should be maintained.
Annual reassessment - H / EMA/S/0000264995	Outcome: 8th annual re-assessment	24/07/2025			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 Orphacol should be maintained.
PSUR / EMA/PSUR/0000321503	EURD: PSUSA/00010590/202510 Active substance: chenodeoxycholic acid (inborn error in primary bile acid synthesis, xanthomatosis - centrally authorised products only) Outcome: Maintenance	07/05/2026			Maintenance