Oxlumo

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
Variation type II /	C.I HUMAN AND VETERINARY MEDICINAL	24/07/2025	04/08/2025	SmPC and PL	

[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).

EMA/VR/0000263375	PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.8, and 5.1 of the SmPC in order update the description of clinical efficacy and safety data based on final results from the Extension Period of study ALN-GO1-004 (ILLUMINATE-B) listed as a category 3 study in the RMP; this is a Phase 3 multicentre, multinational, single-arm, open- label study with an extended dosing period designed to demonstrate the efficacy and safety of lumasiran in reducing urinary and plasma oxalate in PH1 patients <6 years of age and with relatively preserved renal function; In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.				
Variation type IB / EMA/VR/0000278833	B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.z Change in the testing frequency of specification parameter, from routine testing to skip or periodic testing - Accepted	08/07/2025	N/A		

Renewal - 5 year / EMA/R/0000245133	- Renewal - Accepted	18/06/2025	04/08/2025	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 Oxlumo in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUR / EMA/PSUR/0000248463	- -				Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing lumasiran (Oxlumo) remains unchanged and therefore recommends the maintenance of the marketing authorisation(s).