Qaialdo

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 IB /	Outcome:	30/06/2026		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).

EMA/VR/0000347805	C. Safety, efficacy, pharmacovigilance changes - C.z Other variation - Accepted To update sections 2, 4.4 and 6.1 of the SmPC to implement the wording concerning propylene glycol in the EC guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'. The labelling and PL are updated accordingly.			Labelling and PL	
Variation type IB / EMA/VR/0000332066	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Q.II.c) Control of excipients - Q.II.c.z Other variation - Accepted	07/05/2026			
Variation type IA_IN / EMA/VR/0000342406	Outcome: C.3 Change(s) in the summary of product characteristics, labelling or package leaflet intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Article 45 or 46 of Regulation (EC) No 1901/2006, or the outcome of a PRAC signal recommendation, or to adapt to a joint recommendation of EU competent authorities (e.g. a Core SmPC, or	23/04/2026			

	following the assessment of an Urgent Safety Restriction etc.) - C.3.a) Implementation of the agreed wording - Refused				
Variation type IB / EMA/VR/0000333112	Outcome: C.2 Change(s) in the summary of product characteristics, labelling or package leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.2.a) Implementation of change(s) for which no new additional data is required to be submitted by the holder - Accepted C.2.a (Type IB) – To update the SmPC and the PL by including information on the reduction of lithium renal clearance and the monitoring of lithium levels, following approval of the same change for the reference product Aldactone. Furthermore, the unit for serum creatinine was changed throughout the PI from mg/dL to µmol/L. In addition, Section 4.2 of the SmPC was updated to reflect the contraindications already stated in Section 4.3, specifically regarding GFR values and renal impairment in adults and paediatric patients, while also standardizing terminology used for renal impairment and adjusting the order of contraindications in Section 4.3 for consistency. The MAH also took the	24/03/2026		SmPC and PL	To update the SmPC and the PL by including information on the reduction of lithium renal clearance and the monitoring of lithium levels, following approval of the same change for the reference product Aldactone. Furthermore, the unit for serum creatinine was changed throughout the PI from mg/dL to µmol/L. In addition, Section 4.2 of the SmPC was updated to reflect the contraindications already stated in Section 4.3, specifically regarding GFR values and renal impairment in adults and paediatric patients, while also standardizing terminology used for renal impairment and adjusting the order of contraindications in Section 4.3 for consistency. The MAH also took the opportunity to implement editorial changes to the PI to correct typographical errors.

	opportunity to implement editorial changes to the PI to correct typographical errors.				
Variation type IA_IN / EMA/VR/0000326118	Outcome: This was an application for a group of variations. Q.II.b.2.c) Addition or replacement of a site responsible for batch release (QP certification) - Q.II.b.2.c.1 Not including batch control/testing - Accepted Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.a) Addition or replacement of a batch control/testing site applying physicochemical and/or microbiological analytical procedures for the finished product - Accepted Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.a) Addition or replacement of a batch control/testing site applying physicochemical and/or microbiological analytical procedures for the finished product - Accepted Q.II.b.1 Change in the manufacturing site for part or all of the manufacturing process of the finished product (except for batch release and batch control testing sites) - Q.II.b.1.a) Addition or replacement of a site responsible for secondary packaging - Accepted	10/02/2026		Annex II and PL	

Marketing Authorisation Transfer - H / EMA/T/0000304593	Outcome: Transfer of Marketing Authorisation from Nova Laboratories Ireland Limited to Lipomed GmbH	03/11/2025	12/12/2025	SmPC, Labelling and PL	
Variation type IB / EMA/VR/0000286887	Outcome: This was an application for a group of variations. B.IV Medical Devices - B.IV.z Other variation - Accepted B.IV Medical Devices - B.IV.z Other variation - Accepted B.IV Medical Devices - B.IV.z Other variation - Accepted B.IV Medical Devices - B.IV.z Other variation - Accepted B.IV Medical Devices - B.IV.z Other variation - Accepted B.IV Medical Devices - B.IV.z Other variation - Accepted B.IV Medical Devices - B.IV.z Other variation - Accepted B.IV Medical Devices - B.IV.z Other variation - Accepted B.IV Medical Devices - B.IV.z Other variation - Accepted B.IV.1.a Addition or replacement of a device which is not an integrated part of the primary packaging - B.IV.1.a.1 Device with	19/08/2025	12/12/2025	SmPC and PL	

	CE marking - Accepted B.IV.1.a Addition or replacement of a device which is not an integrated part of the primary packaging - B.IV.1.a.1 Device with CE marking - Accepted				
Variation type IB / EMA/VR/0000273846	Outcome: This was an application for a group of variations. B.II.e.6 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - B.II.e.6.b Change that does not affect the product information - Accepted B.II.e.4 Change in shape or dimensions of the container or closure (immediate packaging) - B.II.e.4.a Non-sterile medicinal products - Accepted B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.z Other changes - Accepted	30/06/2025			

Variation type IA_IN / EMA/VR/0000279205	Outcome: B.IV.1.a Addition or replacement of a device which is not an integrated part of the primary packaging - B.IV.1.a.1 Device with CE marking - Accepted	18/06/2025			
Variation type IB / EMA/VR/0000261319	Outcome: B.II.d.2 Change in test procedure for the finished product - B.II.d.2.z Other changes - Accepted	14/04/2025			