



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ARIKAYCE liposomal

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	18/09/2025		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/0000284843	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 section 4.8 of the SmPC in order to add (Pharyngeal swelling, Nasal dryness, Epistaxis, Rhinorrhoea, Sneezing, Nasal Congestion, Dysphagia, Glossitis, Glossodynia, Salivary hypersecretion, Stomatitis, Abdominal pain, Abdominal pain upper, Abdominal discomfort, Abdominal distension) to the list of adverse drug reactions (ADRs) with frequency (Not known) based on post-marketing data. The Package Leaflet is updated accordingly.				
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