

Desloratadine Actavis

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:	02/07/2026		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/0000340641	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 Type IB, C.2.a – to update sections 4.6 and 4.8 of the SmPC and Section 1 of the PIL to align the PI with the one of the reference product Aeries following assessment of the same change via procedure (EMA/VR/0000312765), adopted by CHMP on 26 February 2026. In addition, the MAH took the opportunity to apply editorial/formatting throughout the PI. Moreover, contact details of the local representatives were updated for the following countries: MT, EL, CY, ES, and QRD 10.4 updates were applied to BG, DK, HU, PL. UK (NI) was also removed following QRD update 10.4.			Labelling and PL	
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