EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Desloratadine Actavis

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
IG/1612	A.1 - Administrative change - Change in the name and/or address of the MAH	31/05/2023		SmPC, Labelling and PL	
PSUSA/962/202107	Periodic Safety Update EU Single assessment - desloratadine	24/03/2022	30/05/2022	SmPC and PL	Please refer to Aerius-Azomyr-Neoclarityn-Desloratadine Teva-Dasselta-Desloratadine Actavis-Desloratadine

[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).

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					ratiopharm-EMEA/H/C/PSUSA/00000962/202107 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IAIN/0021/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 - Administrative change - Deletion of manufacturing sites B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	27/02/2022	30/05/2022	SmPC, Annex II and PL	
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/09/2021	30/05/2022	PL	
IB/0018	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	16/04/2020	29/01/2021	SmPC, Annex II, Labelling and PL	

IA/0017	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	22/11/2019	n/a		
IAIN/0016/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	08/08/2019	29/01/2021	Annex II and PL	
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/10/2018	29/01/2021	PL	
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/03/2018	23/04/2018	PL	
IAIN/0013	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	29/11/2017	23/04/2018	SmPC and PL	
PSUSA/962/2	Periodic Safety Update EU Single assessment -	23/03/2017	18/05/2017	SmPC and PL	Refer to Scientific conclusions and grounds recommending

01607	desloratadine				the variation to terms of the Marketing Authorisation(s)' for PSUSA/962/201607.
IB/0012	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	16/05/2017	23/04/2018	SmPC	
IAIN/0011/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	17/02/2017	18/05/2017	Annex II and PL	
IAIN/0010	B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	16/12/2016	n/a		
R/0008	Renewal of the marketing authorisation.	15/09/2016	11/11/2016	SmPC and Labelling	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Desloratadine Actavis in the approved indication remains favourable and therefore recommended the renewal of the

					marketing authorisation with unlimited validity.
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/02/2016	11/05/2016	PL	
IB/0006	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	14/10/2015	11/05/2016	SmPC, Annex II and PL	
IB/0005	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	04/06/2015	11/05/2016	SmPC and PL	
IB/0004/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by	30/04/2015	11/05/2016	SmPC and PL	

	the MAH				
IAIN/0003	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	16/04/2015	n/a		
N/0002	Update of the package leaflet with revised contact details of local representative for Greece, Italy and Portugal. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/08/2014	16/03/2015	PL	
IB/0001/G	This was an application for a group of variations. B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	10/03/2014	16/03/2015	SmPC, Labelling and PL	