EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Desloratadine ratiopharm

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
N/0030	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/06/2022		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 ratiopharm-EMEA/H/C/PSUSA/00000962/202107 EPAR:

[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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					Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IA/0029	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	29/04/2022	n/a		
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/01/2022	30/05/2022	PL	
IA/0026	A.7 - Administrative change - Deletion of manufacturing sites	18/01/2021	27/01/2022	Annex II and PL	
II/0025/G	This was an application for a group of variations. B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a manufacturer of the AS supported by an ASMF B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	14/01/2021	n/a		
II/0023/G	This was an application for a group of variations. C.I.5.b - Change in the legal status of desloratadine ratiopharm from 'medicinal product subject to medical prescription' to 'medicinal product not subject to medical prescription'. As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8 and 5.1 of the SmPC are updated. The annex II, package leaflet and labelling are updated accordingly. Furthermore,	15/10/2020	24/11/2020	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion Desloratadine ratiopharm EMEA/H/C/002404/II/0023/G.

	the product information is brought in line with the latest QRD template (version 10.1) and the list of local representatives in the package leaflet is updated. The RMP is updated to version 1.2. As a consequence of the variation, the pack sizes of 40, 50, 60, 90 and 100 tables are deleted (EU/1/11/746/007-011). C.I.6.b - To delete the therapeutic indication in adolescents aged 12 years and older for the relief of symptoms associated with allergic rhinitis and urticaria. Section 4.1 of the SmPC and section 1 of the PL are updated accordingly. C.I.5.b - Change in the legal status of a medicinal product for centrally authorised products - All other legal status changes C.I.6.b - Change(s) to therapeutic indication(s) - Deletion of a therapeutic indication				
IB/0024	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	14/04/2020	24/11/2020	SmPC	
IB/0022/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time	16/12/2019	n/a		

	data 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				
IA/0021/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	18/10/2019	n/a		
IA/0020/G	This was an application for a group of variations. B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished	20/03/2019	n/a		

	product - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation				
IA/0019/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	30/05/2018	n/a		
IAIN/0018	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	29/11/2017	12/11/2018	SmPC and PL	
PSUSA/962/201607	Periodic Safety Update EU Single assessment - desloratadine	23/03/2017	18/05/2017	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/962/201607.
R/0015	Renewal of the marketing authorisation.	23/06/2016	08/08/2016	SmPC, Labelling and PL	
IB/0014	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale	08/03/2016	21/04/2016	SmPC	

	(supported by real time data)				
IA/0016	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	02/03/2016	n/a		
IA/0013/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.7 - Administrative change - Deletion of manufacturing sites 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	02/03/2016	21/04/2016	Annex II and PL	
IB/0012	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	08/10/2015	21/04/2016	SmPC and Annex II	

IB/0011	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	15/06/2015	21/04/2016	SmPC and PL	
IB/0009/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 the MAH	27/04/2015	21/04/2016	SmPC, Annex II, Labelling and PL	
IA/0010/G	This was an application for a group of variations. B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the	15/04/2015	n/a		

	finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms				
IA/0007	B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)	19/09/2013	01/09/2014	SmPC, Labelling and PL	

II/0005/G	This was an application for a group of variations. This was an application for a group of variations for the PVC/PVdC/aluminium blisters presentations. - To add to the release and shelf-life specifications of the finished product a new specification parameter. - To change the specification limits of "Total impurities" of the finished product at end of shelf-life. - To reduce the shelf-life of the finished product, as packaged for sale, from 3 years to 2 years. - To add a new storage condition of the finished product: "Do not store above 30°C". -To change an analytical method adopted for the specifications of the finished product. In addition the MAH took the opportunity to update section 4.8 of the SmPC in line with the QRD template v9.0, and to amend the phone number of the Irish local representative and add the Hungarian local representative details to the list. The PL was updated accordingly. B.II.d.1.g - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter as a result of a safety or quality issue B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.f.1.a.1 - Stability of FP - Reduction of the shelf life of the finished product - As packaged for sale	19/09/2013	01/09/2014	SmPC, Labelling and PL	

	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
II/0004/G	This was an application for a group of variations. - To modify the Finished Product manufacturing process. - To change the Finished Product batch size. B.II.b.3.b - Change in the manufacturing process of the finished product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the currently approved batch size	25/07/2013	n/a		
IAIN/0006	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	20/06/2013	n/a		
IAIN/0002/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding	16/11/2012	n/a		

	manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits				
IB/0001/G	This was an application for a group of variations. B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	16/08/2012	n/a		