Desloratadine Teva

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
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: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IAIN/0028	B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition	26/07/2021	30/05/2022	SmPC, Labelling and	

[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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	of inks used for product marking - Changes in imprints, bossing or other markings			PL	
IA/0027	A.7 - Administrative change - Deletion of manufacturing sites	10/02/2021	30/04/2021	Annex II and PL	
N/0026	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/06/2020	30/04/2021	PL	
IB/0025	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	15/04/2020	30/04/2021	SmPC, Annex II and PL	
IB/0023/G	This was an application for a group of variations. B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.c.z - Container closure system of the AS - Other variation B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation	13/02/2020	n/a		
IA/0024	B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other	16/01/2020	n/a		

	variation				
N/0022	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/04/2019	30/04/2021	Labelling and PL	
IB/0021	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	02/07/2018	n/a		
N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/03/2018	12/12/2018	PL	
IB/0018/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits	07/03/2018	n/a		

	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.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS				
IB/0019	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	17/01/2018	12/12/2018	SmPC, Labelling and PL	
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/12/2017	12/12/2018	PL	
PSUSA/962/201607	Periodic Safety Update EU Single assessment - desloratadine	23/03/2017	24/05/2017	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/962/201607.
IB/0015/G	This was an application for a group of variations. B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other	07/12/2016	n/a		

	variation B.I.b.z - Change in control of the AS - Other variation B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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.III.2.a.1 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS B.III.2.a.1 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply				

	with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS				
R/0014	Renewal of the marketing authorisation.	23/06/2016	08/08/2016		Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Desloratadine Teva in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0013/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.7 - Administrative change - Deletion of manufacturing sites	04/03/2016	12/05/2016	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	30/10/2015	12/05/2016	SmPC, Annex II and PL	
IB/0011	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	28/08/2015	12/05/2016	SmPC, Labelling and PL	

IB/0010	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	11/06/2015	12/05/2016	SmPC, Labelling and PL	
IB/0009	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	05/05/2015	12/05/2016	SmPC, Annex II, Labelling and PL	
IA/0008/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	17/02/2015	n/a		

	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
T/0007	Transfer of Marketing Authorisation from Teva Pharma B.V. (Utrecht) to Teva B.V. (Haarlem). Transfer of Marketing Authorisation	03/11/2014	01/12/2014	SmPC, Labelling and PL	
IA/0006/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process 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 originally approved batch size	17/09/2014	n/a		
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/06/2014	01/12/2014	PL	
IAIN/0004	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	21/05/2013	n/a		
IA/0003	A.7 - Administrative change - Deletion of manufacturing sites	17/04/2013	n/a		
N/0002	Update of the local representatives contact details for Denmark.	15/01/2013	01/12/2014	PL	

	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)				
IB/0001	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	02/07/2012	29/10/2012	SmPC and PL	Correction of a typographical error in the tablet description in the SmPC and in the PIL for all the product information languages and update of the local representatives contact details for the United Kingdom, Italy and Ireland. The MAH also corrected the pharmaceutical form in the blister labelling for the Lithuanian text and amend the INN of Desloratadine in the Portuguese text.