Luxturna

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
R/0040	Renewal of the marketing authorisation.	25/05/2023	24/07/2023	SmPC, Labelling and PL	
PSUSA/10742 /202207	Periodic Safety Update EU Single assessment - voretigene neparvovec	23/02/2023	26/04/2023	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10742/202207.

[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).

IB/0038/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	22/02/2023	n/a		
IA/0039	A.7 - Administrative change - Deletion of manufacturing sites	19/01/2023	n/a		
IB/0034/G	This was an application for a group of variations. B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	03/11/2022	n/a		
IA/0037	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	17/10/2022	n/a		
IA/0035	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	17/10/2022	n/a		

IB/0033	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)	19/08/2022	26/04/2023	SmPC	
IB/0032	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	28/07/2022	n/a		
IB/0031	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	27/06/2022	n/a		
IA/0030	B.II.z - Quality change - Finished product - Other variation	07/06/2022	n/a		
IB/0029/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation B.I.z - Quality change - Active substance - 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.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	31/05/2022	n/a		

II/0026/G	This was an application for a group of variations. 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.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.z - Quality change - Active substance - Other variation	22/04/2022	n/a		
IB/0028	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	28/02/2022	n/a		To update the RMP with `vision loss due to progressive chorioretinal atrophy' as an important potential risk in the RMP. In addition the MAH has taken the opportunity to make minor administrative and template-related changes to the RMP.
PSUSA/10742 /202107	Periodic Safety Update EU Single assessment - voretigene neparvovec	10/02/2022	n/a		PRAC Recommendation - maintenance
PSUSA/10742 /202101	Periodic Safety Update EU Single assessment - voretigene neparvovec	16/09/2021	09/11/2021	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10742/202101.
IB/0024/G	This was an application for a group of variations. B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	27/10/2021	n/a		

	B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation				
IAIN/0027/G	This was an application for a group of variations. 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	18/10/2021	n/a		
IB/0023	B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	22/07/2021	n/a		
IA/0021/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.7 - Administrative change - Deletion of manufacturing sites	04/03/2021	n/a		
PSUSA/10742 /202007	Periodic Safety Update EU Single assessment - voretigene neparvovec	11/02/2021	n/a		PRAC Recommendation - maintenance

IA/0020	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	16/12/2020	09/11/2021	SmPC and PL	
PSUSA/10742 /202001	Periodic Safety Update EU Single assessment - voretigene neparvovec	17/09/2020	20/11/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10742/202001.
IB/0018/G	This was an application for a group of variations. B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	05/11/2020	n/a		
IB/0017	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	21/10/2020	n/a		
IB/0015/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation B.I.z - Quality change - Active substance - Other variation B.I.z - Quality change - Active substance - Other	03/08/2020	n/a		

	variation B.I.z - Quality change - Active substance - Other variation				
IA/0014/G	This was an application for a group of variations. B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol B.II.f.1.e - Stability of FP - Change to an approved stability protocol	29/05/2020	n/a		
IB/0012/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	11/03/2020	n/a		
PSUSA/10742 /201907	Periodic Safety Update EU Single assessment - voretigene neparvovec	13/02/2020	n/a		PRAC Recommendation - maintenance
IB/0011/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	20/12/2019	09/03/2020	SmPC and PL	

	re-test period/storage period supported by real time data B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol 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) 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) B.II.f.1.e - Stability of FP - Change to an approved stability protocol				
IA/0010	B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test	19/12/2019	n/a		
IB/0009/G	This was an application for a group of variations. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method	18/12/2019	n/a		

IAIN/0008	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	23/10/2019	n/a		
IB/0006/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation B.I.z - Quality change - Active substance - Other variation B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	20/09/2019	n/a		
PSUSA/10742 /201901	Periodic Safety Update EU Single assessment - voretigene neparvovec	05/09/2019	n/a		PRAC Recommendation - maintenance
IB/0004	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	24/04/2019	n/a		
IB/0003	B.II.a.3.b.1 - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients	03/04/2019	n/a		

IAIN/0002/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	28/03/2019	09/03/2020	Annex II and PL	
T/0001	Transfer of Marketing Authorisation	20/12/2018	23/01/2019	SmPC, Labelling and PL	