Sunlenca

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
II/0025	Update of sections 4.2 and 4.4 of the SmPC in order to reinforce the importance of injecting Sunlenca subcutaneously and not intradermally, and to add a new warning on 'Injection Site Reactions with Improper Administration' to describe that intradermal administration has been associated with	30/01/2025		SmPC, Labelling and PL	

[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).

	serious injection site reactions including necrosis and ulcer, based on a cumulative safety review. Moreover, section 4.8 was updated to include necrosis as an example of an injection site reaction. The Package Leaflet is updated accordingly. The Instructions for Use (IFU) of Sunlenca solution for injection have also been updated to improve readability for healthcare professionals. In addition, the MAH took the opportunity to introduce editorial and formatting changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0024/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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 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.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same	26/11/2024	n/a		

	pharmaceutical group as the currently approved manufacturer 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.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				
IB/0021/G	This was an application for a group of variations. B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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 B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch	31/10/2024	n/a		

	release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products				
IB/0020/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.z - Change in control of the Finished Product - Other variation 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.z - Change in control of the Finished Product - Other variation B.I.b.z - Change in control of the AS - Other variation 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	08/10/2024	n/a		
PSUSA/11012 /202402	Periodic Safety Update EU Single assessment - lenacapavir	03/10/2024	n/a		PRAC Recommendation - maintenance
II/0019	Update of section 4.5 of the SmPC in order to include information on co-administration of lenacapavir with systemic dexamethasone based on post-marketing data and literature. In addition, the MAH took the	05/09/2024		SmPC	4.5 is updated to include the dexamethasone drug drug interaction (DDI) with Lenacapavir. Plasma concentrations of lenacapavir may decrease when co-administered with systemic dexamethasone. Caution is advised if Sunlenca is

	opportunity to implement editorial changes to the SmPC. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				coadministered with a sensitive CYP3A and/or P gp substrate with a narrow therapeutic index. For more information, please refer to the Summary of Product Characteristics.
II/0013	Update of section 5.3 of the SmPC in order to include non-clinical information based on final results from study TX-200-2046 entitled, "104 Week Subcutaneous Injection Carcinogenicity and Toxicokinetic Study of GS-6207 Administered Every 13 Weeks in Wistar-Han Rats". In addition, the MAH took the opportunity introduce minor editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/07/2024		SmPC	SmPC new text In this variation, 5.3 of the SmPC is updated to include the results of the life-time (2-year) rat carcinogenicity study where they were exposed to SC-injected lenacapavir every 13 weeks. Moreover, MAH committed to include more injection-site nodule information into SmPC 4.8 within the expected submission of the study GS-US-200-4625 by 30 September 2024. For more information, please refer to the Summary of Product Characteristics.
IB/0015	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	22/04/2024	n/a		
IA/0017/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.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	04/04/2024	n/a		

IA/0016	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	20/03/2024	n/a		
PSUSA/11012 /202308	Periodic Safety Update EU Single assessment - lenacapavir	07/03/2024	n/a		PRAC Recommendation - maintenance
IA/0014	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	08/12/2023	n/a		
IA/0011	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	31/10/2023	n/a		
IB/0010/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.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	26/10/2023	n/a		
IA/0009	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change	04/10/2023	n/a		

	in the manufacturing process				
PSUSA/11012 /202302	Periodic Safety Update EU Single assessment - lenacapavir	28/09/2023	n/a		PRAC Recommendation - maintenance
IB/0008/G	This was an application for a group of variations. 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)	23/06/2023	06/06/2024	SmPC and PL	
IA/0007	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	12/06/2023	n/a		
IB/0006	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	09/06/2023	n/a		
IAIN/0004/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 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	23/02/2023	n/a		

	manufacturer 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				
IA/0003	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	21/11/2022	n/a		
IA/0002	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	19/09/2022	n/a		
IA/0001/G	This was an application for a group of variations. 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 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 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	19/09/2022	n/a		