Ronapreve

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
IA/0016	A.7 - Administrative change - Deletion of manufacturing sites	31/01/2024		Annex II	
PSUSA/10963 /202301	Periodic Safety Update EU Single assessment - casirivimab / imdevimab (Ronapreve)	31/08/2023	n/a		PRAC Recommendation - maintenance

[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).

IA/0012	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	04/07/2023		SmPC	
II/0002	Extension of indication to include treatment of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg and receiving supplemental oxygen, who have a negative SARS-CoV-2 antibody test result for Ronapreve; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 4.9, 5.1 ,5.2 and 6.6 of the SmPC are updated. The variation leads to amendments to the Summary of Product Characteristics, Labelling and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	26/04/2023	26/05/2023	SmPC, Labelling and PL	Please refer to Scientific Discussion 'Ronapreve-H-C-005814-II-002
II/0010/G	This was an application for a group of variations. B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS 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	04/05/2023	n/a		

	B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method				
II/0009	Update of sections 4.4 and 4.8 of the SmPC in order to add a new warning for convulsive syncope to the list of adverse drug reactions (ADRs) with frequency not known, following a signal assessment conducted by MAH. The Package Leaflet is updated accordingly C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	26/01/2023	24/02/2023	SmPC and PL	SmPC new text In the current variation the convulsive syncope is added to sections 4.4 and 4.8 of the SmPC. This has been observed following intravenous and subcutaneous administration. Convulsive syncope is a sign or symptom of infusion-related reactions, hypersensitivity reaction or considered to be part of a vasovagal reflex reaction associated with orthostatic hypotension... Convulsive syncope should be differentiated from seizures and managed as clinically indicated. For more information, please refer to the Summary of Product Characteristics.
PSUSA/10963 /202207	Periodic Safety Update EU Single assessment - casirivimab / imdevimab (Ronapreve)	09/02/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10963 /202201	Periodic Safety Update EU Single assessment - casirivimab / imdevimab (Ronapreve)	01/09/2022	n/a		PRAC Recommendation - maintenance
IB/0006/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.II.d.1.a - Change in the specification parameters	12/07/2022	n/a		

	and/or limits of the finished product - 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.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits 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 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.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits 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 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.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.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits				
IB/0005	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	06/07/2022	n/a		
IA/0004/G	This was an application for a group of variations.	10/05/2022	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.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits				
II/0001	Update of sections 4.1, 4.4 and 5.1 of the SmPC in order to update information on the in vitro neutralization activity of casirivimab/imdevimab against the SARS-CoV-2 B.1.1.529 (Omicron) variant. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	04/03/2022	07/03/2022	SmPC	In vitro data suggest that the SARS-CoV-2 B.1.1.529 (Omicron) variant shows reduced susceptibility against casirivimab/imdevimab (Ronapreve).