GHRYVELIN

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/0023	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	28/02/2024	n/a		

[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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R/0020	Renewal of the marketing authorisation.	12/10/2023	12/01/2024	SmPC	Based on the review of data on quality, safety, and efficacy, the CHMP considered that the benefit-risk balance of GHRYVELIN in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0022	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)	08/01/2024		SmPC	
T/0021	Transfer of Marketing Authorisation	25/08/2023	11/09/2023	SmPC, Labelling and PL	
PSUSA/10746 /202201	Periodic Safety Update EU Single assessment - macimorelin	01/09/2022	n/a		PRAC Recommendation - maintenance
IB/0018	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	09/08/2022	n/a		
IA/0019	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	25/07/2022	n/a		
PSUSA/10746 /202107	Periodic Safety Update EU Single assessment - macimorelin	10/02/2022	n/a		PRAC Recommendation - maintenance
IAIN/0016	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	16/11/2021	09/11/2022	SmPC, Labelling and PL	

PSUSA/10746 /202101	Periodic Safety Update EU Single assessment - macimorelin	02/09/2021	n/a		PRAC Recommendation - maintenance
T/0012	Transfer of Marketing Authorisation	31/03/2021	21/04/2021	SmPC, Labelling and PL	
IAIN/0013	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	30/03/2021	16/04/2021	SmPC, Labelling and PL	
PSUSA/10746 /202007	Periodic Safety Update EU Single assessment - macimorelin	11/02/2021	n/a		PRAC Recommendation - maintenance
IA/0011	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	05/02/2021	n/a		
IA/0009/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process 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 B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other	08/01/2021	n/a		

	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				
IA/0010	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	06/01/2021	n/a		
PSUSA/10746 /202001	Periodic Safety Update EU Single assessment - macimorelin	03/09/2020	n/a		PRAC Recommendation - maintenance
IB/0007/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.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	21/07/2020	n/a		

	does not have a significant effect on the overall quality of the AS				
PSUSA/10746 /201907	Periodic Safety Update EU Single assessment - macimorelin	16/01/2020	n/a		PRAC Recommendation - maintenance
IA/0005/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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.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.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	20/12/2019	n/a		

IA/0003	B.I.c.2.c - Change in the specification parameters and/or limits of the immediate packaging of the AS - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	14/05/2019	n/a		
II/0001	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	02/05/2019	n/a		
IA/0002/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	29/04/2019	n/a		