Nitisinone MDK

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/0013	Renewal of the marketing authorisation.	22/04/2022	15/07/2022	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Nitisinone MDK in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity

[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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IAIN/0014	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	20/06/2022	n/a		
X/0007	Annex I_2.(c) Change or addition of a new strength/potency	14/10/2021	20/12/2021	SmPC, Annex II, Labelling and PL	
PSUSA/2169/ 202102	Periodic Safety Update EU Single assessment - nitisinone	30/09/2021	n/a		PRAC Recommendation - maintenance
IAIN/0011	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	19/10/2020	n/a		
IAIN/0010	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	22/06/2020	17/06/2021	Annex II and PL	
T/0009	Transfer of Marketing Authorisation	18/03/2020	28/04/2020	SmPC, Labelling and PL	
IB/0006/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a	11/09/2019	28/04/2020	SmPC and PL	

	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 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				
IA/0005	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	26/06/2019	n/a		
IB/0003	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	21/06/2019	28/04/2020	SmPC, Labelling and PL	
IA/0004/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 B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor	06/06/2019	n/a		

	changes to an approved test procedure 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 B.II.d.2.a - Change in test procedure for the finished product - 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				
IB/0002/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.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	21/04/2018	20/09/2018	SmPC	
IAIN/0001/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP -	03/10/2017	20/09/2018	SmPC, Annex II, Labelling and PL	

	Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing				