EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Zurampic

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
PSUSA/10470 /201912	Periodic Safety Update EU Single assessment - lesinurad	09/01/2020	n/a		PRAC Recommendation - maintenance
IB/0014	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	11/09/2019	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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IB/0015	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	08/08/2019	n/a		
PSUSA/10470 /201812	Periodic Safety Update EU Single assessment - lesinurad	11/07/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10470 /201712	Periodic Safety Update EU Single assessment - lesinurad	12/07/2018	n/a		PRAC Recommendation - maintenance
IB/0011/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.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	11/06/2018	n/a		
PSUSA/10470 /201706	Periodic Safety Update EU Single assessment - lesinurad	11/01/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10470 /201612	Periodic Safety Update EU Single assessment - lesinurad	06/07/2017	n/a		PRAC Recommendation - maintenance

IA/0008	B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms	15/06/2017	22/02/2018	SmPC, Labelling and PL	
IB/0006	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	28/03/2017	n/a		
IAIN/0005/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.b - Replacement or addition of a manufacturing site for the FP - Primary 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.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.g.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supporting data	09/03/2017	22/02/2018	Annex II, Labelling and PL	
PSUSA/10470 /201606	Periodic Safety Update EU Single assessment - lesinurad	12/01/2017	n/a		PRAC Recommendation - maintenance
II/0002	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission	15/09/2016	n/a		

	of studies to the competent authority				
T/0003	Transfer of Marketing Authorisation	12/08/2016	25/08/2016	SmPC, Labelling and PL	
II/0001	Submission of final study report for retrospective analysis of clinical samples to further characterize the metabolic profile of lesinurad, including metabolite M4 (Category 3 study). C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	16/06/2016	n/a		