Xaluprine

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/1988/201609	Periodic Safety Update EU Single assessment - mercaptopurine	18/05/2017	13/07/2017	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/1988/201609.
R/0012	Renewal of the marketing authorisation.	15/09/2016	18/11/2016	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Xaluprine 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/0013	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	09/06/2016	18/11/2016	SmPC and PL	
IAIN/0011	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	29/07/2015	n/a		
PSUV/0008	Periodic Safety Update	25/09/2014	19/11/2014	SmPC and PL	Please refer to Xaluprine (EMEA/H/C/2022/PSUV/0008) EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IAIN/0010	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	17/10/2014	n/a		
IAIN/0009	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	16/06/2014	n/a		
IAIN/0007	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	21/03/2014	n/a		
PSUV/0006	Periodic Safety Update	24/10/2013	20/12/2013	SmPC and PL	Update of Sections 4.4 and 4.8 of the SmPC to add a warning on hepatosplenic T cell lymphoma and lymphoproliferative disorders and to add the adverse reaction hepatosplenic T cell lymphoma and

					lymphoproliferative disorders with a frequency unknown. The Package leaflet is to be updated accordingly. Please refer to: Xaluprine-H-C-2022-PSUV-0006 EPAR - Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IB/0004	B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data)	11/03/2013	20/12/2013	SmPC, Labelling and PL	
IAIN/0005	B.III.1.a.1 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	05/03/2013	n/a		
II/0002/G	This was an application for a group of variations. The preservative system of the finished product Xaluprine has been revised: changes involve deletion of propyl parahydroxybenzoate and replacement with ethyl parahydroxybenzoate, sodium salt and potassium sorbate, sodium salt of methyl parahydroxybenzoate. In addition revision to the manufacturing process and the test procedures have been performed with the new formulation. B.II.a.3.b.2 - Changes in the composition (excipients) of the finished product - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the product	20/09/2012	15/11/2012	SmPC, Labelling and PL	

	B.II.b.3.z - Change in the manufacturing process 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.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation				
IAIN/0003	B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	15/08/2012	n/a		
IAIN/0001	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	11/05/2012	15/11/2012	SmPC, Labelling and PL	