Jayempi

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
PSUR / EMA/PSUR/0000257799	Cardiac dysfunction (as part of hypersensitivity reactions) In view of	24/07/2025	17/09/2025	SmPC and PL	Variation

[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).

	available data on cardiac dysfunction (as part of hypersensitivity reactions) from the literature, including in seven cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between azathioprine and cardiac dysfunction (as part of hypersensitivity reactions) is at least a reasonable possibility. The PRAC concluded that the product information of products containing azathioprine should be amended accordingly. Cholestasis of pregnancy In view of available data on cholestasis of pregnancy from the literature, spontaneous reports including in eight cases a close temporal relationship and a positive de-challenge, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between azathioprine and cholestasis of pregnancy is at least a reasonable possibility. The PRAC concluded that the product information of products containing azathioprine should be amended accordingly. Pellagra / nicotinic acid deficiency In view of available data on pellagra from the literature, including 8 literature cases with a close temporal relationship and a positive de-challenge, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between azathioprine and pellagra is at least				

	a reasonable possibility. The PRAC concluded that the product information of products containing azathioprine should be amended accordingly. Posterior reversible encephalopathy syndrome (PRES) In view of available data on posterior reversible encephalopathy syndrome from the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between azathioprine and posterior reversible encephalopathy syndrome is at least a reasonable possibility. The PRAC concluded that the product information of products containing azathioprine should be amended accordingly. Sialoadenitis In view of available data on sialoadenitis from the literature, including 5 cases with a close temporal relationship, and a positive de-challenge and re-challenge, the PRAC considers a causal relationship between azathioprine and sialoadenitis is at least a reasonable possibility. The PRAC concluded that the product information of products containing azathioprine should be amended accordingly. Tremor In view of available data on tremor from the literature and spontaneous reports, including in some cases a close temporal relationship and a positive de-challenge and/or re-challenge,				

	the PRAC considers a causal relationship between azathioprine and tremor is at least a reasonable possibility. The PRAC concluded that the product information of products containing azathioprine should be amended accordingly. Drug-drug interaction between azathioprine and allopurinol In view of available data on the interaction between azathioprine and allopurinol from spontaneous reports, the PRAC considers an amendment of the existing wording warranted. The PRAC concluded that the product information of products containing azathioprine should be amended accordingly.				
Variation type IA_IN / EMA/VR/0000257074	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment - Accepted	19/03/2025	17/09/2025	SmPC, Labelling and PL	To update sections 4.4 and 4.8 of the SmPC and sections 2 and 4 of the PL to implement the signal recommendations on 'zathioprine – Non-cirrhotic portal hypertension / portosinusoidal vascular disease (EPITT no 20091)' adopted at the 28 November 2024 PRAC.
Variation type IA / EMA/VR/0000244745	B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer – Accepted	14/01/2025	N/A		