



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Arsenic trioxide medac

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
Variation type IB /	C.2 Change(s) in the summary of product	21/04/2026		SmPC and PL	

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).



EMA/VR/0000338900	<p>characteristics, labelling or package leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.2.a) Implementation of change(s) for which no new additional data is required to be submitted by the holder - Accepted</p> <p>C.9 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.9.a) Implementation of changes to reflect the outcome of previous assessment - Accepted</p> <p>C.2.a (Type IB) – To update section 4.8 of the SmPC with safety information based on the final results from PASS C18477-ONC-50025 listed as a category 3 study in the RMP, following assessment of the same change for the reference product Trisenox. In addition, the PI is brought in line with the latest QRD template version 10.4, and the date of the latest renewal is added. C.9.a (Type IB) – To update the RMP to align the safety concerns with those of the reference product Trisenox. The following safety concerns were removed: Important potential risk (Carcinogenicity) and Missing information (Long term safety).</p>				
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