

Summary of risk management plan for Arsenic Trioxide Mylan (Arsenic Trioxide)

This is a summary of the risk management plan (RMP) for Arsenic Trioxide Mylan. The RMP details important risks of Arsenic Trioxide Mylan, how these risks can be minimised, and how more information will be obtained about Arsenic Trioxide Mylan 's risks and uncertainties (missing information).

Arsenic Trioxide Mylan's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Arsenic Trioxide Mylan should be used.

This summary of the RMP for Arsenic Trioxide Mylan should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Arsenic Trioxide Mylan's RMP.

I. The medicine and what it is used for

ARSENIC TRIOXIDE MYLAN is authorised for induction of remission, and consolidation in adult patients with:

- Newly diagnosed low-to-intermediate risk acute promyelocytic leukaemia (APL) (white blood cell count, $\leq 10 \times 10^3/\mu\text{l}$) in combination with all-trans-retinoic acid (ATRA)
- Relapsed/refractory acute promyelocytic leukaemia (APL) (Previous treatment should have included a retinoid and chemotherapy)
- characterised by the presence of the t(15;17) translocation and/or the presence of the Pro-Myelocytic
- Leukaemia/Retinoic-Acid-Receptor-alpha (PML/RAR-alpha) gene.

The response rate of other acute myelogenous leukaemia subtypes to arsenic trioxide has not been examined.

It contains arsenic trioxide as the active substance, and it is given intravenously.

Further information about the evaluation of Arsenic Trioxide Mylan's benefits can be found in Arsenic Trioxide Mylan's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's [webpage](#).

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Arsenic Trioxide Mylan, together with measures to minimise such risks and the proposed studies for learning more about Arsenic Trioxide Mylan's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine’s legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Arsenic Trioxide Mylan is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Arsenic Trioxide Mylan are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Arsenic Trioxide Mylan. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	None
Important potential risks	• Carcinogenicity
Missing information	• Long-term safety

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Arsenic Trioxide Mylan.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Arsenic Trioxide Mylan.