Part VI: Summary of the risk management plan

Summary of risk management plan for Diazepam Macure (diazepam)

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

Diazepam Macure summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Diazepam Macure should be used.

Important new concerns or changes to the current ones will be included in updates of Diazepam Macure's RMP.

I. The medicine and what it is used for

Diazepam Macure is authorised for treatment in adults of

- anxiety
- seizures
- alcohol withdrawal symptoms
- premedication before surgical or diagnostic procedure
- anaesthesia initiation and conscious anaesthesia
- spasms related to tetanus

Diazepam Macure is authorised for treatment in paediatric patients of

- seizures

- premedication before surgical or diagnostic procedure
- spasms related to tetanus

It contains 5 mg/ml diazepam as the active substance, and it is given by injection.

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

Important risks of Diazepam Macure, together with measures to minimise such risks and the proposed studies for learning more about Diazepam Macure'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*.

II.A List of important risks and missing information

Important risks of Diazepam Macure are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered or taken. 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 Diazepam Macure. 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.

Summary of safety concerns	
Important identified risk	None
Important potential risks	None
Missing information	None