Part VI: Summary of the risk management plan

Summary of risk management plan for Lorazepam Macure (lorazepam)

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

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

I. The medicine and what it is used for

Lorazepam Macure is authorised as a sedative to initiate certain interventions (premedication), such as small or large surgical procedures or certain extensive physical examinations. It is also used for people who suffer from severe fears or tension and for any reason cannot take any tablets and for status

epilepticus (see SmPC for the full indication). It contains lorazepam as the active substance and it is given by intravenous or intramuscular administration.

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

Important risks of Lorazepam Macure, together with measures to minimise such risks and the proposed studies for learning more about Lorazepam 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 pharmaceutical form (e.g. solution for injection) — limits the access only to healthcare professionals;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with 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 Lorazepam Macure is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Lorazepam 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. 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 Lorazepam 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.

Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected.

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	Use in pregnant women

II.B Summary of important risks

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

Missing information – Use in pregnant women	
Risk minimisation measures	Routine risk minimisation measures: - SmPC section 4.6. - Pharmaceutical form: solution for injection. - Legal status: prescription only medicine.

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 Lorazepam Macure.

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

There are no studies required for Lorazepam Macure.