

Part VI: Summary of the risk management plan

Summary of risk management plan for Midazolam Aguettant (Midazolam)

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

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

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

I. The medicine and what it is used for

Midazolam Aguettant is authorised for conscious sedation before and during diagnostic or therapeutic procedures with or without local anaesthesia, anaesthesia, and sedation in intensive care units (see SmPC for the full indication). It contains midazolam as the active substance, and it is given by intravenous, intramuscular injection or rectal.

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

Important risks of Midazolam Aguettant, together with measures to minimise such risks and the proposed studies for learning more about Midazolam Aguettant '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, including PSUR assessment 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 Midazolam Aguettant 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 Midazolam Aguettant. 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);

Table 3: List of important risks and missing information

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

II.B Summary of important risks

None.

II.C Post-authorisation development plan

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

There is no study which is conditions of the marketing authorisation or specific obligation.

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

There is no study required.