Part VI: Summary of the risk management plan

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

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

I. The medicine and what it is used for

Lidocaine 10 mg/ml solution for injection in pre-filled syringe and Lidocaine 20 mg/ml solution for injection in pre-filled syringe are indicated in local anaesthesia, peripheral nerve block and intravenous regional anaesthesia for upper extremities (see SmPC for the full indication). They contain lidocaine as the active substance and they are given by intravenous injection (intravenous use) or infiltration (intradermal, subcutaneous, or submucosal use) injection into the surroundings of peripheral nerves.

Lidocaine Aguettant 20 mg/mL, solution for injection/infusion is indicated in infiltration anaesthesia, intravenous regional anaesthesia, nerve blocks and epidural anaesthesia. It contains lidocaine as the active substance and it is given by intravenous, subcutaneous infiltration or epidural injection.

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

Important risks of Lidocaine Aguettant, together with measures to minimise such risks and the proposed studies for learning more about Lidocaine 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.

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

II.A List of important risks and missing information

Important risks of Lidocaine 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 Lidocaine 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

List of important risks and missing information	
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 are no studies which are conditions of the marketing authorisation or specific obligation.

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

There are no studies required for Lidocaine Aguettant.