Part VI: Summary of the risk management plan

Summary of risk management plan for Lidocaine Adrenaline (s) (< Lidocaine hydrochloride – Adrenaline tartrate

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

<Invented name>'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how <invented name> should be used.

Important new concerns or changes to the current ones will be included in updates of <invented name>'s RMP.

I. The medicine and what it is used for

<Invented name> is authorised for local or regional anaesthesia. Lidocaine Adrenaline Aguettant 10 mg/ml + 5 mcg/ml is intended for adults and children over 1 year. Lidocaine Adrenaline Aguettant 20 mg/ml + 5 mcg/ml is intended for adults and adolescents over 12 years (see SmPC for the full indication). It contains lidocaine hydrochloride and adrenaline (epinephrine) tartrate as the active substance and it is given by infiltration anaesthesia, intravenous regional anaesthesia, nerve block or epidural anaesthesia.

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

Important risks of <invented name >, together with measures to minimise such risks and the proposed studies for learning more about <invented name>'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 <invented name> 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 <invented name>. 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 risiks 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 is no study which is conditions of the marketing authorisation or specific obligation of <invented name>.

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

There is no study required for <invented name>.