Part VI: Summary of the risk management plan

Summary of risk management plan for

Lidocaine Grindeks (Livohep) 10 mg/ml solution for injection

Lidocaine Grindeks (Livohep) 20 mg/ml solution for injection

(Lidocaine hydrochloride)

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

Lidocaine Grindeks (Livohep) summary of product characteristics (SPC) of and its package leaflet give essential information to healthcare professionals and patients on how Lidocaine Grindeks (Livohep) should be used.

Important new concerns or changes to the current ones will be included in updates of Lidocaine Grindeks's (Livohep's) RMP.

I. The medicine and what it is used for

Lidocaine Grindeks (Livohep) is authorised for intravenous regional anaesthesia, infiltration anaesthesia, nerve blocks and epidural anaesthesia. Lidocaine Grindeks (Livohep) is indicated in adults. It contains lidocaine hydrochloride as the active substance in concentration of 10 mg or 20 mg per 1 milliliter.

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

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

If important information that may affect the safe use of Lidocaine hydrochloride Baltijos Bite is not yet available, it is listed under "missing information" below.

II.A *List of important risks and missing information*

Important risks of Lidocaine hydrochloride Baltijos Bite 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 hydrochloride Baltijos Bite. 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).

Summary of safety concerns	
Important identified risks	Hypersensitivity, including anaphylaxis Central nervous system toxicity Cardiac toxicity
Important potential risks	Methaemoglobinaemia
Missing information	Use in paediatric patients Use during pregnancy

II.B Summary of important risks

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

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 Lidocaine hydrochloride Baltijos Bite.

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

There are no studies required for Lidocaine hydrochloride Baltijos Bite.