Part VI: Summary of the risk management plan

Summary of risk management plan for LIDBREE (lidocaine 42 mg/mL) intrauterine gel)

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

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

I. The medicine and what it is used for

LIDBREE is authorised for Topical anaesthesia for cervical and intrauterine procedures, such as placement of intrauterine contraceptive devices, in adults and adolescents (see SmPC for the full indication). It contains the local anaesthetic lidocaine as the active substance and it is given by cervical and intrauterine administration to women.

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

Important risks of LIDBREE, together with measures to minimise such risks and the proposed studies for learning more about LIDBREE'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 LIDBREE 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 LIDBREE. 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);

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable as there are no important risks identified.

II.C Post-authorisation development plan

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

Not applicable.

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

Not applicable

This RMP was written based on the EMA 2017 Rev.2 template for Risk Management Plan. (30 March 2017, EMA/PRAC/613102/2015 Rev.2)