Part VI: Summary of the risk management plan

Summary of risk management plan for

Instillido 20 mg/ml gel in pre-filled syringe

(Lidocaine hydrochloride monohydrate 20 mg/ml gel)

This is a summary of the risk management plan (RMP) for Instillido 20 mg/ml gel in pre-filled syringe. The RMP details important risks of the product, and how more information will be obtained about the risks and uncertainties (missing information) of Instillido 20 mg/ml gel in pre-filled syringe.

The summary of product characteristics (SmPC) and the package leaflet (PL) of Instillido 20 mg/ml gel in pre-filled syringe give essential information to healthcare professionals and patients on how the product should be used.

Important new concerns or changes to the current ones will be included in updates of the RMP for Instillido 20 mg/ml gel in pre-filled syringe.

I. The medicine and what it is used for

Instillido is authorised for surface anaesthesia and lubrication for urethral and rectal use (see SmPC for the full indication). It contains lidocaine hydrochloride monohydrate as the active substance and it is given by instillation.

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

Important risks of Instillido 20 mg/ml gel in pre-filled syringe, together with measures to minimise such risks and the proposed studies for learning more about these 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, 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 Instillido 20 mg/ml gel in pre-filled syringe 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 Instillido 20 mg/ml gel in pre-filled syringe. 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

Important identified risks

Not applicable, there are no important risks.

Important potential risks

Not applicable, there are no important risks.

Missing information

Not applicable, there is no missing information.

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 Instillido 20 mg/ml gel in pre-filled syringe.

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

There are no studies required for Instillido 20 mg/ml gel in pre-filled syringe.