PART VI: Summary of the risk management plan

Summary of risk management plan for ChloraPrep™ (chlorhexidine gluconate and isopropyl alcohol)

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

ChloraPrep's product information gives essential information to healthcare professionals and patients on how ChloraPrep products should be used.

I. The medicine and what it is used for

ChloraPrep is authorised for the disinfection of the patient's skin prior to surgery, invasive medical procedures and injection in the EU and additionally also for the maintenance of device insertion sites in other countries (see product information for the full indication). It contains chlorhexidine gluconate and isopropyl alcohol as active substances and it is intended for cutaneous use.

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

Important risks of ChloraPrep, together with measures to minimise such risks and the proposed studies for learning more about ChloraPrep' s risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

1. Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and product information addressed to patients and healthcare professionals
2. Important advice on the medicine's packaging;
3. The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
4. 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. ChloraPrep products are administered in a clinical setting by healthcare professionals.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including the assessment from the periodic safety update reports 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 ChloraPrep is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

ChloraPrep does not have any important identified or potential risks, or 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

Not applicable.

II.C Post-authorisation development plan

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

There are no studies which conditions of the marketing authorisation or specific obligation of ChloraPrep.

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

There are no studies required for ChloraPrep.