

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN FOR CHLORHEXIDINE 40 mg/ml CUTANEOUS SOLUTION

This is a summary of the risk management plan (RMP) for Chlorhexidine 40 mg/ml Cutaneous Solution. The RMP details important risks of Chlorhexidine 40 mg/ml Cutaneous Solution, how these risks can be minimised, and whether more information will be obtained about the risks and uncertainties (missing information).

The Chlorhexidine 40 mg/ml Cutaneous Solution Summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Chlorhexidine 40 mg/ml Cutaneous Solution should be used.

Important new concerns or changes to the current ones will be included in updates of the prescribing information and this RMP for Chlorhexidine 40 mg/ml Cutaneous Solution.

I. The medicine and what it is used for

Chlorhexidine 40 mg/ml Cutaneous Solution is an antiseptic solution that is used for cleansing and disinfecting the hands before surgery and in hospital wards, for bathing and disinfecting the skin before and after a surgical operation, and for routine hand cleansing / disinfecting of the skin to help prevent the spread of infections.

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

Important risks of Chlorhexidine 40 mg/ml Cutaneous Solution, together with measures to minimise such risks are outlined below in Sections II.A and II.B.

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 approved 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 types of measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures are called *routine pharmacovigilance activities*.

II.A List of important risks and missing information

'Important risks' of Chlorhexidine 40 mg/ml Cutaneous Solution are risks that need special risk management activities to further investigate or minimise the risk, so that the medicine can be safely used.

Important risks can be regarded as 'Identified' or 'Potential':

- Identified risks are concerns for which there is enough proof of a link with the use of Chlorhexidine 40 mg/ml Cutaneous Solution.
- 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).

The safety profile of chlorhexidine is very well established.

There are no additional safety concerns specific to the use of Chlorhexidine 40 mg/ml Cutaneous Solution.

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.

Summary of missing information

Not applicable.

II.C Post-authorisation development plan

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

Not applicable.

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

Not applicable.