Part VI: Summary of the risk management plan

Summary of risk management plan for chlorhexidine digluconate

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

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

Important new concerns or changes to the current ones will be included in updates of chlorhexidine digluconate's RMP.

I. The medicine and what it is used for

Chlorhexidine digluconate is authorized as an antiseptic for wounds and minor skin burns, and for new-borns belly button. It contains chlorhexidine digluconate as the active substance and it is given by cutaneous route of administration.

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

The safety profile of chlorhexidine digluconate is well characterised and the safety concerns are considered not important for inclusion in the RMP. Therefore, considering that there are no important risks of chlorhexidine digluconate, this section is not applicable.

II.A List of important risks and missing information

Important risks of chlorhexidine digluconate 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 chlorhexidine digluconate. 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.

II.C Post-authorisation development plan

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

There are no studies which are conditions of the marketing authorization or specific obligations of chlorhexidine digluconate.

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

There are no studies required for chlorhexidine digluconate.