Summary of risk management plan for povidone-iodine products

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

Povidone-iodine products' summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how povidone-iodine products should be used.

Important new concerns or changes to the current ones will be included in updates of povidoneiodine products' RMP.

I. The medicine and what it is used for

Povidone-iodine products are authorised for the repeated, temporally limited application as an antiseptic for the prevention and treatment of infections in situations such as preoperative skin preparation of the operative site, disinfection of wounds, skin, genital and oropharyngeal mucosa and anti-infective prophylaxis during hospital and office procedures.

All povidone-iodine products contain povidone-iodine as the active substance and are applied in a variety of formulations, including cutaneous, oromucosal and vaginal solution, gel, pessary, ointment, cream, tincture, scalp and/or skin cleanser, impregnated dressing, soap, shampoo, scrub, mouthwash and gargle.

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

Important risks of povidone-iodine products, together with measures to minimise such risks and the proposed studies for learning more about povidone-iodine products' 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 povidone-iodine products 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 povidone-iodine products. 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

The safety information in the proposed Product Information is aligned to the reference medicinal product.

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 povidone-iodine products.

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

There are no studies required for povidone-iodine products.