PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN FOR FORTACIN (LIDOCAINE / PRILOCAINE)

This is a summary of the risk management plan (RMP) for Fortacin cutaneous spray, solution (150 mg/ml lidocaine / 50 mg/ml prilocaine). The RMP details important risks of Fortacin, how these risks can be minimised, and how more information will be obtained about Fortacin's risks and uncertainties (missing information).

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

This summary of the RMP for Fortacin should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones are included in updates of Fortacin's RMP.

I. The medicine and what it is used for

Fortacin is authorised for the treatment of primary premature ejaculation in adult men. It contains lidocaine and prilocaine as the active substances and it is given topically as a cutaneous spray. A single dose of Fortacin (3 actuations) consists of a total of 22.5 mg lidocaine and 7.5 mg prilocaine.

Further information about the evaluation of Fortacin's benefits can be found in Fortacin's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

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

Important risks of Fortacin, together with measures to minimise such risks and the proposed studies for learning more about Fortacin 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;

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.

If important information that may affect the safe use of Fortacin is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Fortacin 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

Fortacin. 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).

There are currently no important (identified and potential) risks and mission information that warrant additional review other than maintenance of the routine pharmacovigilance activities for Fortacin.

II.B Summary of important risks

There are no applicable important risks.

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 obligations of Fortacin.

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

There are no studies required for Fortacin.