PART V: RISK MINIMISATION MEASURES (INCLUDING EVALUATION OF THE EFFECTIVENESS OF RISK MINIMISATION ACTIVITIES)

Risk Minimisation Plan

V.1. Routine Risk Minimisation Measures

Not Applicable

V.2 Additional Risk Minimisation Measures

None

V.3 Summary of risk minimisation measures

Not applicable

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Permethrin 5.0 % w/w Cream (Permethrin):

This is a summary of the risk management plan (RMP) for Permethrin 5.0 % w/w Cream. The RMP details important risks of Permethrin 5.0 % w/w Cream, how these risks can be minimised, and how more information will be obtained about Permethrin 5.0 % w/w Cream risks and uncertainties (missing information).

Permethrin 5.0 % w/w Cream, summary of product characteristics (SmPC) and package leaflet (PL) give essential information to healthcare professionals and patients on how Permethrin 5.0 % w/w Cream should be used.

Important new concerns or changes to the current ones will be included in updates of Permethrin 5.0 % w/w Cream RMP.

I. The medicine and what it is used for

Permethrin 5.0 % w/w Cream is indicated for the treatment of scabies in adults and children >2 months of age. Additionally, it is indicated for the treatment of crab lice in adults in the United Kingdom.

It contains permethrin as the active substance and is applied topically.

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

Important risks of Permethrin 5.0 % w/w Cream, together with measures to minimise such risks and the proposed studies for learning more about Permethrin 5.0 % w/w Cream 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 PL 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 Periodic Safety Update Report (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 Permethrin 5.0 % w/w Cream are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Permethrin 5.0 % w/w Cream. 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 risk	• None
Missing information	• None

II.B Summary of important risks

Important identified risks

None

Important potential risks

None

Missing information

None

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 Permethrin 5.0 % w/w Cream.