PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Scopoderm (hyoscine)

This is a summary of the Risk Management Plan (RMP) for Scopoderm. The RMP details important risks of Scopoderm, how these risks can be minimized, and how more information will be obtained about Scopoderm's risks and uncertainties (missing information). Scopoderm's Summary of Product Characteristics (SmPC) and Package Leaflet (PL) give essential information to healthcare professionals and patients on how Scopoderm should be used.

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

I. The medicine and what it is used for

Scopoderm is authorized for the treatment of motion sickness. It contains hyoscine as the active substance, and it is a transdermal patch to be applied topically.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

The important risks of Scopoderm, together with measures to minimize such risks and the proposed studies for learning more about Scopoderm's risks are outlined below. Measures to minimize the risks identified for any 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 authorized pack size – the amount of medicine in a pack is chosen so as 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).

Together, these measures constitute *routine risk minimization measures*.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 Scopoderm are risks that need special risk management activities to further investigate or minimize 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 Scopoderm. Potential risks are concerns for which an association with the use of the medicinal product is possible based on available data, but this association has not been established yet and needs to be further monitored. Missing information refers to information on the safety of the medicinal product that is currently missing and further information may need to be collected (e.g., on the long-term use of the medicine).

There are no important risks or missing information included in the RMP for Scopoderm.

List of important risks and missing information	
Important identified risks	None.
Important potential risks	None.
Missing information	None.

II.B Summary of important risks and missing information

Not applicable.

II.C Post-authorization 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 Scopoderm.

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

There are no studies required for Scopoderm.