Part VI: Summary of the risk management plan

The content of this part is the same for all invented names of doxylamine succinate/ pyridoxine hydrochloride covered by this RMP. Only one Summary of the risk management plan is presented for all of them.

Summary of the risk management plan for doxylamine succinate / pyridoxine hydrochloride

This is a summary of the risk management plan (RMP) for doxylamine succinate/ pyridoxine hydrochloride. The RMP details important risks of doxylamine succinate/ pyridoxine hydrochloride, how these risks can be minimised, and how more information will be obtained about Doxylamine/ Pyridoxine risks and uncertainties (missing information).

Doxylamine succinate/ pyridoxine hydrochloride summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Doxylamine/Pyridoxine should be used.

Important new concerns or changes to the current ones will be included in updates of Doxylamine/Pyridoxine RMP.

I. The medicine and what it is used for

Doxylamine succinate/ pyridoxine hydrochloride is authorised for treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management (see SmPC for the full indication). It contains doxylamine succinate and pyridoxine hydrochloride as the active substances and it is given by the oral route of administration.

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

Important risks of doxylamine succinate/ pyridoxine hydrochloride, together with measures to minimise such 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 doxylamine succinate/ pyridoxine hydrochloride 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 doxylamine succinate/ pyridoxine hydrochloride. 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).

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable

There are no important identified or potential risks on the list of safety concerns.

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 doxylamine/pyridoxine.

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

There are no studies required for doxylamine/pyridoxine.