# Part VI: Summary of the risk management plan

Summary of risk management plan for Provocholine (methacholine chloride).

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

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

## *I. The medicine and what it is used for*

Provocholine is indicated in adults and children (5 years old and above) for the diagnosis of bronchial airway hyper-reactivity in patients who do not have clinically apparent asthma (see SmPC for the full information). It contains methacholine chloride as the active substances, and it is prepared from powder and given for inhalation administration. All dilutions must be made with 0.9% sodium chloride injection, containing 0.4% phenol (pH = 7.0), using empty, sterile borosilicate Type I glass vials. After adding the sodium chloride solution, shake each vial to obtain a clear solution.

Further information about the evaluation of provocholine's benefits can be found in methacholine'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 methacholine chloride, 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.

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

## II.A List of important risks and missing information

Important risks of provocholine 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 provocholine. 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

Not applicable.

## 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 methacholine.

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

There are no studies required for methacholine.