

Summary of risk management plan for Fenylefrin Abcur/ Phenylephrine Injection (herein referred as Phenylephrine).

This is a summary of the risk management plan (RMP) for Phenylephrine. The RMP details missing information of Phenylephrine, and how more information will be obtained about Phenylephrine uncertainties (missing information). Phenylephrine's summary of product characteristics (SmPC) and its package leaflet (PIL) give essential information to healthcare professionals and patients on how Phenylephrine should be used.

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

I. The medicine and what it is used for

Phenylephrine 0.05 mg/ml and 0.1 mg/ml injection is indicated in adults for the treatment of hypotension during general anaesthesia.

Phenylephrine 10 mg/ml injection is indicated in adults and children for the treatment of hypotensive states e.g., circulatory failure, during spinal anaesthesia or drug induced hypotension.

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

Important risks of Phenylephrine, together with measures to minimise such risks and the proposed studies for learning more about Phenylephrine's 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 will be 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 Phenylephrine 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 Phenylephrine. 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 as no safety concerns are proposed.

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 for Phenylephrine injection.

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

There are no studies required for Phenylephrine injection.