

Part VI: Summary of the risk management plan

Summary of risk management plan for <invented name> (phenylephrine)

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

<Invented name>'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how <invented name> should be used.

I. The medicine and what it is used for

<Invented name> is authorised for treatment of hypotension during spinal, epidural or general anaesthesia and for prevention of spinal anaesthesia induced hypotension during caesarean section (see SmPC for the full indication). It contains phenylephrine as the active substance and it is given by intravenous bolus injection or by intravenous continuous infusion.

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

Important risks of <invented name>, together with measures to minimise such risks and the proposed studies for learning more about <invented name>'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 the case of <invented name>, these measures are not supplemented with *additional risk minimisation measures*.

If important information that may affect the safe use of <invented name> is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of <invented name> are risks that need special risk management activities to further investigate or minimise 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 <invented name>. 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).

Table 1: List of important risks and missing information

| List of important risks and missing information | |
|--|--------------------------------|
| Important identified risks | Hypersensitivity Arrhythmia |
| Important potential risks | Extravasation |
| Missing information | Use in paediatric population |

II.B Summary of important risks

Table 2: Summary of important risks

| Important Identified Risk: Hypersensitivity | |
|--|--|
| Evidence for linking the risk to the medicine | Hypersensitivity is a well-known side effect of phenylephrine, mainly described when locally administered in the eye; however, hypersensitivity reactions can also occur when administered via parenteral route |
| Risk factors and risk groups | Patients with medical history of local allergic reaction related to phenylephrine eye drop may develop general hypersensitivity reaction when administered via parenteral route. |
| Risk minimisation measures | Routine risk minimisation measures <ul style="list-style-type: none">- SmPC section 4.3 and 4.8.- PL section 2 and 4 Additional risk minimisation measures <ul style="list-style-type: none">- None |

| Important Identified Risk: Arrhythmia | |
|---|--|
| Evidence for linking the risk to the medicine | Arrhythmia is a well-known side effect of phenylephrine described in the literature. |
| Risk factors and risk groups | Patients with coronary heart disease and chronic heart conditions, underlying bradycardia and partial heart block. |
| Risk minimisation measures | Routine risk minimisation measures <ul style="list-style-type: none"> - SmPC section 4.4, 4.5 and 4.8. - PL section 2 and 4 Additional risk minimisation measures <ul style="list-style-type: none"> - None |

| Important Potential Risk: Extravasation | |
|--|---|
| Evidence for linking the risk to the medicine | Irritating properties of phenylephrine are well-known and described in the literature. |
| Risk factors and risk groups | Unknown |
| Risk minimisation measures | Routine risk minimisation measures <ul style="list-style-type: none"> - SmPC section 4.4 and 4.8. - PL section 4 Additional risk minimisation measures <ul style="list-style-type: none"> - None |

| Missing information: use in paediatric population | |
|--|--|
| Risk minimisation measures | Routine risk minimisation measures <ul style="list-style-type: none"> - SmPC section 4.2 - PL section 2 Additional risk minimisation measures <ul style="list-style-type: none"> - 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 <invented name>.

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

There are no studies required for <invented name>