
VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

During anaesthesia the patient undergoing anaesthesia may experience a reduction in normal blood pressure (typically ≥ 20% decrease from normal blood pressure), i.e. hypotension. It is estimated that one-third of patients undergoing spinal anaesthesia experience hypotension. This hypotension during spinal anaesthesia is considered to be due to decrease in amount of blood returned to the heart and due to reduction in amount of blood pumped out of heart.
Hypotension may also occur after general anaesthesia. Prolonged hypotension during anaesthesia is associated with increased mortality and also unwanted side effects related to both heart and other bodily systems. Therefore, during the surgery restoration of blood pressure is the immediate requirement. Increased or normalised BP is the appropriate endpoint for a drug such as ephedrine which acts by tightening blood vessels.

Hypotension is one of the most important causes of nausea and vomiting particularly in the initial period after initiation of spinal anaesthesia.

VI.2.2 Summary of treatment benefits

Ephedrine is a cardiac stimulant with mixed action effect on the central nervous system. Hypotension is a common side effect of spinal anaesthesia. Phenylephrine and ephedrine are the

two most frequently used vasopressors to treat spinal hypotension. There is no clear evidence that either medication is more effective at maintaining blood pressure or has a superior safety profile 12. Ephedrine is on the World Health Organization's List of Essential Medicines, the most effective and safe medicines needed in a health system. The product has been on the marked for more than 60 years, and its safety profile is well established.

VI.2.3 Unknowns relating to treatment benefits

Animal studies on the effect on fertility are incomplete.

There are no or limited data from use of ephedrine in pregnant women. Ephedrine shall not be used during pregnancy unless the clinical condition of the mother requires treatment. Ephedrine passes the placenta and this has been connected with an increase in the fetal heart rate and heart frequency variability.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
Arrhythmia	Ephedrine is known to cause arrhythmia	Warning about this risk and increased risk in patients with cardiac diseases are included in the SmPC and PIL.

Important potential risks

Risk	**What is known (Including reason why it is considered a potential risk)**
Arterial hypertension	In the literature, arterial hypertension is reportedly associated with ephedrine.

Missing information

Risk	**What is known**
Use in children below 1 year of age	There is a lack of information concerning the efficacy and safety of ephedrine when used in children below 1 year of age. Use of ephedrine is therefore not recommended for children less than 1 year, and healthcare professionals should be aware of this fact.
Risk	**What is known**
Effects on fertility and pregnancy	There is no adequate data from clinical trials for use of ephedrine in pregnant women. Animal studies are insufficient with respect to effects on pregnancy, foetal development, parturition or postnatal

Risk	What is known
	development. The potential risk for humans is unknown. Ephedrine should not be used during pregnancy unless clearly necessary.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for ephedrine can be found in the ephedrine's EPAR page.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

Not Applicable.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable as this is the first RMP.