

## **VI.2 Elements for a Public Summary**

### **VI.2.1 Overview of disease epidemiology (Maximum 150 words per indication)**

Hypotension during anaesthesia is a serious situation. Hypotension is reported in 5 to 76 % of spinal anaesthesia or epidural anaesthesia. Many mechanisms have been suggested to explain the high incidence and severity of hypotension during caesarean delivery performed under spinal anaesthesia.

Risk factors for hypotension in the context spinal anaesthesia or epidural anaesthesia are implicating:

- Increasing age
- High body mass index
- High block
- High ASA (American Society of Anesthesiologists) physical status classification system
- Pregnancy
- Arterial hypertension,
- Chronic alcoholism
- Emergency of surgery

Large doses of local anaesthetics are also reported as a risk factor of hypotension.

### **VI.2.2 Summary of treatment benefits**

Phenylephrine is a well-established use product and its benefits are widely described in the scientific literature.

In current practice, ephedrine is a sympathomimetic agent most commonly used in the treatment and prevention of hypotension under anaesthesia. Phenylephrine is a possible alternative in practice often used in second-line in case of insufficient efficacy of ephedrine.

### **VI.2.3 Unknowns relating to treatment benefits (1 short paragraph per indication of 50 words maximum)**

No extended information is available regarding the use of phenylephrine in paediatric population.

#### VI.2.4 Summary of safety concerns

##### Important identified risks

Risk	What is known	Preventability
High blood pressure (hypertension)	Administration of phenylephrine may lead to an increase in blood pressure	Yes, by titration (process of gradually adjusting the dose of phenylephrine until optimal results are reached) As mentioned in the PIL and the SmPC, Phenylephrine should not be administered in case of severe high blood pressure, and caution is required in case of arterial hypertension.
Irregular heartbeat (Arrhythmia)	Phenylephrine may cause irregular heartbeat	As mentioned in the PIL and in the SmPC, Phenylephrine should be administered with caution in case of heart disease such as heart rhythm disorders.

##### Important potential risks

Risk	What is known	Preventability
Accidental administration of the medicine outside the vein (Extravasation)	Accidental administration of the medicine outside the vein (Extravasation) may cause a death of cells (necrosis) in the tissue surrounding the vein used for the injection	Particular attention should be paid to Phenylephrine injection to avoid extravasation.

##### Missing information

Missing information	What is known	Preventability
Use in children (Use in paediatric population)	No information is currently available concerning use in children.	In the absence of reliable data, the use of injectable phenylephrine is not recommended in children

#### VI.2.5 Summary of risk minimisation measures by safety concern

This medicine has no additional risk minimisation measures.

#### VI.2.6 Planned post authorisation development plan

None.

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

Major changes to the Risk Management Plan over time: not applicable.