

## Part VI: Summary of the risk management plan

### Summary of risk management plan for Bupivacaine Spinal Tung EQL Pharma

This is a summary of the risk management plan (RMP) for Bupivacaine Spinal Tung EQL Pharma. The RMP details important risks of Bupivacaine Spinal Tung EQL Pharma and how more information will be obtained about Bupivacaine Spinal Tung EQL Pharma's risks and uncertainties (missing information).

Bupivacaine Spinal Tung EQL Pharma's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Bupivacaine Spinal Tung EQL Pharma should be used.

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

Bupivacaine Spinal Tung EQL Pharma is authorised for spinal anaesthesia for surgery (see SmPC for the full indication). It contains bupivacaine hydrochloride as the active substance and it is given by injection in the spinal channel.

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

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 is collected continuously and regularly analysed 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 Bupivacaine Spinal Tung EQL are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely injected. 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 Bupivacaine Spinal Tung EQL. 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);

<b>List of important risks and missing information</b>	
Important identified risks	Systemic toxicity CNS and cardiovascular toxicity Consequences of accidental intravascular injection Neurological damage such as paralysis and motor weakness
Important potential risks	None
Missing information	None

## ***II.B Summary of important risks***

The safety information in the proposed product information is aligned to the reference medicinal product.

## ***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 Bupivacaine Spinal Tung EQL Pharma 5 mg/ml solution for injection.

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

There are no studies required for Bupivacaine Spinal Tung EQL Pharma 5 mg/ml solution for injection.