Part VI: Summary of the risk management plan

Summary of risk management plan for Ropivacaine-HCL 2 mg/ml, 5 mg/ml, 7.5 mg/ml, 10 mg/ml Solution for Injection & Ropivacaine-HCL 2 mg/ml Solution for infusion (ropivacaine)

This is a summary of the risk management plan (RMP) for Ropivacaine-HCL 2 mg/ml, 5 mg/ml, 7.5 mg/ml, 10 mg/ml Solution for Injection and Ropivacaine-HCL 2 mg/ml Solution for infusion (hereinafter referred to as ROPIVACAINE). The RMP details important risks of ROPIVACAINE, how these risks can be minimised, and how more information will be obtained about ROPIVACAINE's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Each strength of ROPIVACAINE is authorised for:

2 mg/ml Solution for Injection

Acute pain management:

In adults and adolescents above 12 years of age for:

- Continuous epidural infusion or intermittent bolus administration during postoperative or labour pain
- Field blocks
- Continuous peripheral nerve block via a continuous infusion or intermittent bolus injections, e.g. postoperative pain management

In infants from 1 year and children up to and including 12 years of age (per- and postoperative):

- Single and continuous peripheral nerve block

In neonates, infants and children up to and including 12 years of age for (per- and postoperative):

- Caudal epidural block
- Continuous epidural infusion

5 mg/ml Solution for Injection

In adults for:

- Intrathecal administration for surgical anaesthesia

In infants from 1 year and children up to and including 12 years of age for acute pain management (per and post operative):

- Single peripheral nerve block

7.5 mg/ml Solution for Injection

In adults and adolescents aged above 12 years of age for surgical anaesthesia:

- Epidural blocks for surgery, including Caesarean section
- Major nerve blocks
- Field blocks

10 mg/ml Solution for Injection

In adults and adolescents aged above 12 years of age for surgical anaesthesia:

Epidural blocks for surgery

2 mg/ml Solution for infusion

Acute pain management:

In adults and adolescents above 12 years of age for:

- Continuous epidural infusion or intermittent bolus administration during postoperative or labour pain
- Field blocks (e.g. minor nerve blocks and infiltration)
- Continuous peripheral nerve block via a continuous infusion or intermittent bolus injections, e.g. postoperative pain management

In infants from 1 year and children up to and including 12 years of age for (per- and postoperative):

- Single and continuous peripheral nerve block

In neonates, infants and children up to and including 12 years of age for (per- and postoperative):

- Caudal epidural block
- Continuous epidural infusion

(see SmPC for the full indication).

It contains ropivacaine hydrochloride as the active substance and is it given by epidural, perineural or intrathecal route.

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

Important risks of ROPIVACAINE, together with measures to minimise such risks and the proposed studies for learning more about ROPIVACAINE'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 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 ROPIVACAINE 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 ROPIVACAINE. 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).

List of important risks and missing information	
Important identified risks	None
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 ROPIVACAINE.

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

There are no studies required for ROPIVACAINE.