Part VI: Summary of the risk management plan

Summary of risk management plan for Ropivacaine Hikma 2 mg/mL | 5 mg/mL | 7.5 mg/mL | 10 mg/mL solution for injection (Ropivacaine)

This is a summary of the risk management plan (RMP) for Ropivacaine Hikma 2 mg/mL | 5 mg/mL | 7.5 mg/mL | 10 mg/mL solution for injection. The RMP details important risks of Ropivacaine Hikma 2 mg/mL | 5 mg/mL | 7.5 mg/mL | 10 mg/mL solution for injection, and how more information will be obtained about Ropivacaine Hikma 2 mg/mL | 5 mg/mL | 7.5 mg/mL | 10 mg/mL solution for injection's risks and uncertainties (missing information).

Ropivacaine Hikma 2 mg/mL | 5 mg/mL | 7.5 mg/mL | 10 mg/mL solution for injection's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ropivacaine Hikma 2 mg/mL | 5 mg/mL | 7.5 mg/mL | 10 mg/mL solution for injection should be used.

Important new concerns or changes to the current ones will be included in updates of Ropivacaine Hikma 2 mg/mL | 5 mg/mL | 7.5 mg/mL | 10 mg/mL solution for injection's RMP.

I. The medicine and what it is used for

Ropivacaine Hikma 2 mg/mL solution for injection is indicated for 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.

Ropivacaine Hikma 5 mg/mL solution for injection is indicated 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

Ropivacaine Hikma 7.5 mg/mL solution for injection is indicated 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

Ropivacaine Hikma 10 mg/mL solution for injection is indicated in adults and adolescents aged above 12 years of age for: Surgical anaesthesia:

- Epidural blocks for surgery

They contain ropivacaine as the active substance. The products Ropivacaine Hikma 2 mg/mL | 7.5 mg/mL | 10 mg/mL solution for injection are intended for epidural administration and for nerve and field blocks. The product Ropivacaine Hikma 5 mg/mL solution for injection is intended for intrathecal administration and peripheral nerve block.

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

Important risks of Ropivacaine Hikma 2 mg/mL | 5 mg/mL | 7.5 mg/mL | 10 mg/mL solution for injection, together with measures to minimise such risks and the proposed studies for learning more about Ropivacaine Hikma 2 mg/mL | 5 mg/mL | 7.5 mg/mL | 10 mg/mL solution for injection'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 Hikma 2.5 mg/mL | 5 mg/mL | 7.5 mg/mL | 10 mg/mL solution for injection 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 Hikma 2.5 mg/mL | 5 mg/mL | 7.5 mg/mL | 10 mg/mL solution for injection. 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 Hikma 2 mg/mL | 5 mg/mL | 7.5 mg/mL | 10 mg/mL solution for injection.

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

There are no studies required for Ropivacaine Hikma 2 mg/mL | 5 mg/mL | 7.5 mg/mL | 10 mg/mL solution for injection.

Part VII: Annexes

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Annex 1 – EudraVigilance Interface

Not applicable.

Annex 2 – Tabulated summary of planned, ongoing, and completed pharmacovigilance study programme

Not applicable.

Annex 3 - Protocols for proposed, on-going and completed studies in the pharmacovigilance plan

Not applicable.

Annex 4 - Specific adverse drug reaction follow-up forms

Not applicable.

Annex 5 - Protocols for proposed and on-going studies in RMP part IV

Not applicable.

Annex 6 - Details of proposed additional risk minimisation activities (if applicable)

Not applicable.

Annex 7 - Other supporting data (including referenced material)

(1) PubChem; Ropivacaine; PubChem CID: 175805; Available at (accessed on 21/10/2024): https://pubchem.ncbi.nlm.nih.gov/compound/175805

(2) DrugBank; Ropivacaine; DrugBank Accession Number: DB00296; Available at (accessed on 21/10/2024): https://go.drugbank.com/drugs/DB00296

(3) CMDh; List of safety concerns per approved Risk Management Plan (RMP) of active substances per product July 2025; CMDh_330_2015_Rev37_2025_07; Available at (accessed on 17/09/2025): https://www.hma.eu/464.html

Annex 8 – Summary of changes to the risk management plan over time

Version	**Approval date** **Procedure**	**Change**
0.2	Initial submission	- Update according to the most recent product information.
0.1	Initial submission	Initial RMP submission