# Part VI: Summary of the risk management plan

## Summary of risk management plan for Ampres/Clorotekal 20 mg/ml (chloroprocaine hydrochloride)

This is a summary of the risk management plan (RMP) for Ampres/Clorotekal 20 mg/ml. The RMP details important risks of Ampres/Clorotekal 20 mg/ml, how these risks can be minimised, and how more information will be obtained about Ampres/Clorotekal's risks and uncertainties (missing information).

Ampres/Clorotekal's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ampres/Clorotekal 20 mg/ml should be used.

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

Ampres/Clorotekal 20 mg/ml is authorised for perineural anaesthesia (single peripheral nerve block) in adults for short-duration surgeries (not exceeding 60 minutes) (see SmPC for the full indication).

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

Important risks of Ampres/Clorotekal 20 mg/ml together with measures to minimise such risks and the proposed studies for learning more about Ampres/Clorotekal '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, including PSUR assessment, 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 Ampres/Clorotekal 20 mg/ml 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 Ampres/Clorotekal 20 mg/ml. 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);

| **Summary of safety concerns** | |
|---|---|
| **Important identified risks** | Acute systemic toxicity |
| **Important potential risks** | None |
| **Missing Information** | None |

## *II.B Summary of important risks*

| **Acute systemic toxicity** | |
|---|---|
| Evidence for linking the risk to the medicine | The risk of systemic toxicity due to an involuntary i.v. injection is inferior than with the other local anaesthetics because plasma esterases hydrolyse chloroprocaine rapidly. The in vitro plasma half- life of chloroprocaine in adults is 21 ± 2 seconds for males and 25 ± 1 seconds for females. Chloroprocaine is the elective drug for IVRA (intravenous regional anaesthesia).<br>In presence of a cholinesterase deficit, systemic undesirable effects may occur as the half-life of Chloroprocaine is decelerated. In the case of accidental intravenous administration, the toxic effect occurs within 1 minute. The systemic toxicity is potential life threatening for the patient. |
| Risk factors and risk groups | Patients with genetic deficiency of plasma cholinesterase |
| Risk minimisation measures | Routine risk minimisation measures<br>*SmPC Section 4.2, 4.4, 4.8 and 4.9*<br>*SmPC Section 4.2 where advice is given on how to correctly administer chloroprocaine and avoid risk of acute systemic toxicity*<br>*SmPC Section 4.4 and Section 4.9 where the advice is given on how manage symptoms of acute toxicity following inadvertent intravascular injection* |

## *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 Ampres/Clorotekal 20 mg/ml.

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

There are no studies required for Ampres/Clorotekal 20 mg/ml.