Summary of the Risk Management Plan for Ampres Intrathecal

Ampres Intrathecal, solution injectable (Chloroprocaine Hydrochloride)

Marketing Authorization Holder: Sintetica SA

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Disclaimer

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.
The RMP summary of AMPRES INTRATHECAL is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.
Please note that the reference document which is valid and relevant for the effective and safe use of AMPRES INTRATHECAL in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Sintetica SA is fully responsible for the accuracy and correctness of the content of the published summary RMP of AMPRES INTRATHECAL.

Summary of risk management plan for Ampres Intrathecal (Chloroprocaine Hydrochloride)

I. The medicine and what it is used for

Ampres Intrathecal is authorised for spinal anaesthesia in adults where the planned surgical procedure should not exceed 40 minutes (see SmPC for the full indication). It contains chloroprocaine hydrochloride as the active substance and it is given by intrathecal route.

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

Important risks of Ampres Intrathecal, together with measures to minimise such risks and the proposed studies for learning more about Ampres Intrathecal'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 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 Intrathecal 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 Intrathecal. 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	• Acute systemic toxicity • High/Total spinal block
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). 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 *SmPC Section 4.2, 4.4, 4.8 and 4.9* *SmPC Section 4.2 where advice is given on how to correctly administer chloroprocaine and avoid risk of acute systemic toxicity.* *SmPC Section 4.4 and Section 4.9 where the advice is given on how manage symptoms of acute toxicity following inadvertent intravascular injection*

High/Total spinal block	
Evidence for linking the risk to the medicine	The high/total spinal block occurred when an epidural dose is inadvertently administered intrathecally due to the fact that epidural dose can be 4 to 10-fold higher that the intrathecal dose. Total spinal block leads to consequent cardiovascular and respiratory depression, which are potential life-threatening for the patient.
Risk factors and risk groups	The risk is not correlated to specific risk groups.
Risk minimisation measures	Routine risk minimisation measures *SmPC Section 4.4 and 4.8* *SmPC Section 4.4 where the advice is given on how manage symptoms of acute toxicity following inadvertent intrathecal injection of an epidural dose of chloroprocaine (10-fold higher than spinal dose).*

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 Intrathecal.

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

There are no studies required for Ampres Intrathecal.