

Part VI: Summary of the risk management plan

Summary of risk management plan for ZETACAIN 2% with adrenaline 1:100.000.

This is a summary of the risk management plan (RMP) for ZETACAIN 2% with adrenaline 1:100.000. The RMP details important risks of ZETACAIN 2% with adrenaline 1:100.000 how these risks can be minimised, and how more information will be obtained about ZETACAIN 2% with adrenaline 1:100.000's risks and uncertainties (missing information).

ZETACAIN 2% with adrenaline 1:100.000's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how ZETACAIN 2% with adrenaline 1:100.000 should be used.

Important new concerns or changes to the current ones will be included in updates of ZETACAIN 2% with adrenaline 1:100.000's RMP.

I. The medicine and what it is used for

ZETACAIN 2% with adrenaline 1:100.000 is a pharmaceutical product used as local anaesthetics in odontoiatric field in Europe from some decenniums. Mepivacaine is particularly useful in cardiopathic patients or with blood pressure problems, in fact, the low concentration of vasoconstrictor doesn't increase the side effects in these group of at risk patients. The tolerability of mepivacaine, at recommended dose, is optimum, and only rarely no relevant side effects are reported from clinical point of view. Finally, the combination of mepivacane hydrochloride with a vasoconstrictor, L-Adrenaline, allows a duration of anaesthesia from 45 to 75 min, depending on the vasoconstrictor concentration itself. It is possible to conclude that the efficacy and safety of mepivacaine in dentistry are amply documented.

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

risks Important risks of ZETACAIN 2% with adrenaline 1:100.000, together with measures to minimise such risks and the proposed studies for learning more about ZETACAIN 2% with adrenaline 1:100.000, 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.

If important information that may affect the safe use of ZETACAIN 2% with adrenaline 1:100.000 is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of ZETACAIN 2% with adrenaline 1:100.000 are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 ZETACAIN 2% with adrenaline 1:100.000. 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	Toxic reactions (cardiovascular or neurological) due to overdose or rapid intravenous injections Allergic reactions
Important potential risks	Foetotoxicity
Missing information	Not applicable

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal products.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorisation or specific obligation of mepivacaine/adrenaline.

II.C.2 Other studies in post-authorisation development plan There are no studies required for mepivacaine/adrenaline.

VI.2.5 Summary of additional risk minimisation measures by safety concern

Zetacain have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

VI.2.6 Planned post authorisation development plan (if applicable)

Not applicable.

VI.2.7 Summary of changes to the risk management plan over time

Not applicable.