

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Citanest with Octapressin Dental Solution for Injection Prilocaine Hydrochloride 3% w/v Felypressin 0.54 micrograms/ml.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains Prilocaine Hydrochloride 30 mg (66 mg/2.2 ml cartridge) and Felypressin 0.54 micrograms/ml (1.19 micrograms/2.2 ml cartridge).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A clear, colourless, sterile aqueous solution for injection supplied in clear Type 1 Ph. Eur. Glass cartridges

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Citanest with Octapressin Dental is a local anaesthetic solution for use in dental infiltration and all dental nerve block techniques.

4.2 Posology and method of administration

In normal healthy adults the usual dose is 1-5 ml. Children under 10 years of age require approximately 1 -2 ml. A dose of 10 ml (5 cartridges) of Citanest with Octapressin Dental should not be exceeded.

Elderly or debilitated patients require smaller doses.

4.3 Contraindications

Known hypersensitivity to anaesthetics of the amide type or to any other component of the solution.

Citanest should be avoided in patients with anaemia or congenital or acquired methaemoglobinaemia.

4.4 Special warnings and precautions for use

Great caution must be exercised to avoid accidental intravascular injection of this compound, since it may give rise to the rapid onset of toxicity, with marked restlessness, twitching, or convulsions, followed by coma with apnoea and cardiovascular collapse.

In common with other local anaesthetics, Citanest should be used cautiously in the elderly, patients in poor health, in patients with epilepsy, severe or untreated hypertension, impaired cardiac conduction, severe heart disease, impaired respiratory function and in patients with liver or kidney damage, if the dose or site of administration is likely to result in high blood levels.

Facilities for resuscitation should be available when local anaesthetics are administered.

Local anaesthetics should be avoided when there is inflammation in the region of the proposed injection.

Citanest with Octapressin Dental contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium free'. This should be taken into consideration in patients who are following a reduced-salt diet.

4.5 Interactions with other medicinal products and other forms of interaction

Patients receiving concomitant therapy with sulphonamides e.g. cotrimoxazole are at increased risk of developing methaemoglobinaemia.

The vasopressor properties of octapressin should be borne in mind.

Prilocaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type anaesthetics, since the toxic effects are additive.

4.6 Fertility, pregnancy and lactation

Although there is no evidence of harm to the foetus, as with all drugs Citanest with Octapressin Dental should not be given in early pregnancy unless the benefits are considered to outweigh the risks. Prilocaine enters the mother's milk, but there is generally no risk of effects on the infant at recommended doses.

4.7 Effects on ability to drive and use machines

Citanest with Octapressin Dental has no influence on the ability to drive or use machines.

4.8 Undesirable effects

In common with other local anaesthetics, adverse reactions to Citanest are extremely rare in dental practice and are usually the result of excessively high blood concentrations due to inadvertent intravascular injection, excessive dosage, rapid absorption or occasionally to hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient.

In such circumstances systemic effects occur involving the central nervous system and/or the cardiovascular system.

CNS reactions are excitatory and/or depressant, and may be characterised by nervousness, dizziness, blurred vision and tremors, followed by drowsiness, convulsions, unconsciousness and possibly respiratory arrest, the excitatory reactions may be brief or may not occur at all, in which case the manifestations of toxicity may be drowsiness, merging into unconsciousness and respiratory arrest. Cardiovascular reactions are depressant and may be characterised by hypotension, myocardial depression, bradycardia and possible cardiac arrest.

Allergic reactions are extremely rare. They may be characterised by cutaneous lesions, urticaria, oedema or anaphylactoid reactions. Detection of sensitivity by skin testing is of doubtful value.

This product gives rise to methaemoglobinaemia in a dose related fashion. Clinically significant levels of methaemoglobin may occur with cyanosis when doses of prilocaine exceed 600 mg.

Methaemoglobinaemia may occur at lower doses of prilocaine in patients suffering from anaemia, from congenital or acquired haemoglobinopathy (including methaemoglobinaemia), or in patients receiving concomitant therapy e.g. sulphonamides, known to cause such conditions. Infants are particularly susceptible, due to a lower activity of the enzyme which reduces methaemoglobin to haemoglobin.

Methaemoglobinaemia may be treated by the intravenous administration of a 1% solution of methylene blue at a dose of 1 mg/kg, over a 5 minute period.

4.9 Overdose

Treatment of a patient with systemic toxicity consists of arresting convulsions and ensuring adequate ventilation with oxygen, if necessary by assisted or controlled ventilation (respiration). If convulsions occur they must be treated promptly by intravenous injection of thiopentone 100 to 200 mg or diazepam 5 to 10 mg. If cardiac arrest occurs effective cardiopulmonary resuscitation must be instituted. This should include external cardiac compression, artificial ventilation with oxygen, adrenaline and sodium bicarbonate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anaesthetics, local, amides, ATC code: N01BB54

Local anaesthetics act by preventing transmission of impulses along nerve fibres and at nerve endings; depolarisation and ion-exchange are inhibited. The effects are reversible.

5.2 Pharmacokinetic properties

Prilocaine hydrochloride is absorbed more slowly than lignocaine (lidocaine) because of its slight vasoconstrictor action but its half life in blood is less than that of lignocaine (lignocaine half life approximately 10 minutes, elimination half life approximately 2 hours).

Amidases in the liver and kidney metabolise prilocaine directly.

5.3 Preclinical safety data

Prilocaine hydrochloride is a well established active ingredient

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium hydroxide
Hydrochloric acid
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Glass (2.2 ml) standard cartridges in boxes of 50 or 100.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

For single use only. Discard any unused contents after first use.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 04690/0028

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/07/2006

10 DATE OF REVISION OF THE TEXT

14/09/2016