Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Injection
A clear, colourless, sterile aqueous solution supplied in clear Type I Ph. Eur. glass standard cartridges.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In dental procedures for the production of local analgesia by infiltration and by nerve block, where a vasoconstrictor effect is desirable.

4.2 Posology and method of administration

The usual dose is 1-2ml. The recommended maximum dose is 600mg (10 cartridges) in a healthy adult. Children and elderly or debilitated patients require smaller doses.

Injections should always be made slowly with careful aspiration before, and intermittently during injection to avoid inadvertent intravascular injection, which may have toxic effects.

The lowest dose that results in effective anaesthesia should be used. The dose will also depend on the oral cavity to be anaesthetized, the vascularity of the oral tissue and technique of anaesthesia. The total dose must be adjusted for the size, age and physical status of the patient.

Due to the specific need for bone penetration dental local anaesthetics contain high concentrations of the active agent. Combination of a high pressure and rapid rate of injection may lead to complications especially following accidental intravascular injection.

4.3 Contraindications

Hypersensitivity to the active ingredients or to amide anaesthetics.

Use in infants.

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

4.4 Special warnings and precautions for use

In common with other local anaesthetics, Citanest should be used cautiously in patients with severe and untreated hypertension, patients in poor general condition, severe anaemia, circulatory failure, children, elderly patients, epilepsy, impaired cardiac conduction, 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.

The effect of local anaesthetics may be reduced if an injection is made into an inflamed or infected area.

Use on one patient during one treatment only. Discard unused contents.

The patient should be advised to exercise caution to avoid inadvertent trauma to the lips, tongue, cheek mucosa and palate when these structures are anaesthetized. Ingestion of food should therefore be postponed until normal function returns.

This medicinal product contains less than 1mmol sodium (23mg) per dose i.e. essentially sodium free.

4.5 Interaction with other medicinal products and other forms of interactions

Drugs which may predispose to methaemoglobin formation, (e.g. sulfonamides such as cotrimoxazole, antimalarials and certain nitric compounds), could potentiate this adverse effect of prilocaine.

Prilocaine should be used with caution in patients receiving other local anaesthetics, anti-arrhythmics 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 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 effect on the infant at recommended doses.

Methaemoglobinaemia in the neonate has been reported after the administration of prilocaine to the mother in doses exceeding 600mg.

4.7 Effects on ability to drive and use machines

No effects are foreseen.

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 first 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 possibly 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.

Clinically significant levels of methaemoglobin may occur with cyanosis when doses of prilocaine exceed 600mg.

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 1mg/kg over five minutes.

Headache, nausea, palpitations, raised blood pressure, dyspnoea, contusion, mouth ulceration, injection site necrosis have very rarely been reported.

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 200mg or diazepam 5 to 10mg. Alternatively succinylcholine 50 to 100mg i.v. may be used providing the clinician is capable of performing endotracheal intubation and managing a fully paralysed patient. If cardiac arrest occurs effective cardiopulmonary resuscitation must be instituted. This should include external cardiac compression, artificial ventilation with oxygen, adrenaline and sodium bicarbonate.

Methaemoglobinaemia may be treated by the intravenous administration of 1% solution of methylene blue at a dose of 1mg/kg over five minutes.

This dose should not be repeated as methylene blue in high concentrations acts as a haemoglobin oxidant.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anaesthetics, local, amides.

Citanest 3% with Octapressin Dental contains the local anaesthetic prilocaine and the vasoconstrictor felypressin.

Prilocaine is a local anaesthetic of the amide type. It stabilises the neuronal membrane and prevents the initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. It is less toxic than lidocaine. The doses required to produce toxic symptoms of the CNS are, for example, 30-50% higher with prilocaine than with lidocaine.

Felypressin is a synthetic hormone of the posterior pituitary lobe characterised by vasopressin-like properties. It is used as a vasoconstrictive agent in dental local anaesthetic solutions as an alternative to sympathomimetic agents (e.g. adrenaline). Felypressin has a low toxicity and is well tolerated by the tissues.

5.2 Pharmacokinetic properties

Citanest with Octapressin Dental has a rapid onset of action after infiltration blockade, with an average of 2-3 minutes. Mandibular blockade requires 5 minutes or more for full effect. The duration of effective anaesthesia varies in individuals and depends on the type of blockade. The average duration of useful anaesthesia after infiltration is 45 minutes. After successful regional blockade, e.g. mandibular blockade, anaesthesia persists for 2 hours or longer.

The local ischaemic effect is less pronounced with felypressin and is not followed by tissue hypoxia and cyanosis as is the case with solutions containing adrenaline.

Felypressin in the doses used in Citanest with Octapressin Dental does not interact with tricyclic antidepressant drugs.

Prilocaine is metabolised in the liver, kidneys and lungs. One of the metabolites of prilocaine is o-toluidine, which has been found to induce an increase in the amount of methaemoglobin in the blood.

The mean elimination half-life after the i.v. injection of prilocaine is about 1.5 hours. Prilocaine crosses the blood-brain and the placenta barriers. Hepatic or renal insufficiency may affect the elimination of prilocaine and lead to the accumulation of prilocaine and/or its metabolites.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to that already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium hydroxide
Hydrochloride acid
Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.
For single use only. Discard any unused contents after use.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Type I (Ph. Eur), clear colourless glass cartridge with a standard rubber plunger and an aluminium cap with either a chlorobutyl and natural rubber blend liner or a chlorobutyl rubber liner. The cartridge contains 2.2ml of a clear colourless sterile aqueous solution.

Pack size 2.2 ml: 50 or 100 cartridges. Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use only. Discard any unused contents after use.

7 MARKETING AUTHORISATION HOLDER

DENTSPLY DeTrey GmbH
De-Trey-Strasse 1
78467 Konstanz
Germany

8 MARKETING AUTHORISATION NUMBER

PA1045/001/001

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10 DATE OF REVISION OF THE TEXT

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