Prescribing Information

4% Citanest® Forte Dental with Epinephrine 1:200,000
Prilocaine and Epinephrine Injection, USP
40 mg/mL + 5 µg/mL

Local Anesthetic

Dentsply Canada
161 Vinyl Court
Woodbridge, Ontario
L4L 4A3

DATE OF PREPARATION:
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DATE OF REVISION:

Control#: 137347

DESCRIPTION:

Prilocaine (2-propylamino-o-propionotoluidide) a hydrochloride salt, is a white crystalline odourless power soluble in water and resistant to acid and alkaline hydrolysis. Dental cartridges of 4% Citanest® Forte with Epinephrine 1:200,000 should not be autoclaved since Epinephrine may be altered by heat.

Each mL of 4% Citanest® Forte with Epinephrine 1:200,000 contains the following:

Prilocaine HCl USP	40mg
Epinephrine	0.005 mg
Sodium Metabisulfite	0.5 mg
Citric Acid	0.2 mg
Sodium Hydroxide or Hydrochloride Acid	to adjust pH
Water for injection USP	q.s. 1 mL

ACTIONS:

Prilocaine stabilizes the neuronal membrane and therefore prevents the initiation and transmission of nerve impulses thereby producing anesthesia of about one hour duration in most cases. Anaesthesia is very rapid on onset and more profound and longer than Prilocaine 4% without a vasoconstrictor. Prilocaine, because of its non-ester chemical structure, is not detoxified by circulating plasma esterases.

INDICATION:

4% Citanest Forte with Epinephrine 1:200,000 is indicated for the production of local anaesthesia for dental procedures by nerve block or infiltration injection.

CONTRAINDICATIONS:

Prilocaine is contraindicated in patients with a known hypersensitivity (allergy) to amide type local anaesthetics and those patients with congenital or idiopathic methemoglobinemia. Epinephrine is contraindicated by hypertension, thyrotoxicosis, diabetes, and certain cardiovascular disorders.

Methemoglobinemia studies carried out on experimental animals and man indicate that Prilocaine is capable of producing methemoglobinemia. However, the normal dosage of 1-2 mL in dentistry would not be capable of producing methemoglobinemia, which is statistically significant.

WARNING:

Resuscitative equipment and drugs should be immediately available when any local anaesthetic is used.

The American Heart Association has made the following recommendations regarding the use of local anesthetics with vasoconstrictors in patients with ischemic heart disease: "Vasoconstrictor agents should be used in local anesthesia solutions during dental practice only when it is clear that the procedure will be shortened or the analgesia rendered more profound. When a vasoconstrictor is indicated, extreme care should be taken to avoid intravascular injection. The minimum possible amount of vasoconstrictor should be used." (Kaplan, EL, editor: Cardiovascular disease in dental practice, Dallas 1986, American Heart Association.)

PRECAUTIONS:

4% Citanest Forte with Epinephrine 1:200,000, as with all local anaesthetics containing a vasoconstrictor, should be used with great caution in patients receiving drugs known to produce blood pressure alterations (i.e. MAO inhibitors, tricyclic antidepressants, phenothiazines, etc.) as either severe and sustained hypotension or hypertension may occur. The safety and effectiveness of Prilocaine depends on proper dosage, correct technique, adequate precautions and readiness for emergencies.

The lowest dose that results in effective anaesthesia should be used to avoid high plasma levels and serious undesirable side effects. Injection of repeated doses of the drug may cause significant increases in blood levels, as the drug or its metabolites tend to accumulate. Tolerance varies with the status of the patient. Debilitated, elderly patients, acutely ill patients, and children should be given reduced doses depending on their age and physical status. Solutions containing a vasoconstrictor should be used with caution in the presence of diseases which may adversely affect the cardiovascular

system. The drug should be used with caution in persons with known drug sensitivities. Care should

be used to avoid intravascular injection. Aspiration before and during injection is suggested. Slow injection (not over 1 mL per minute) is important to avoid systemic reactions.

Serious cardiac arrythmias may occur if solutions containing a vasoconstrictor are used along with administration of chloroform, halothane, cyclopropane, trichloroethylene, or similar agents.

ADVERSE REACTIONS:

Adverse experiences following the administration of prilocaine are similar in nature to those observed with other amide-type local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels (which may be caused by excessive dosage, rapid absorption, unintended intravascular injection or slow metabolic degradation), injection technique, volume of injection, hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature.

Reactions involving the central nervous system are characterized by excitation and/or depression. Nervousness, dizziness, blurred vision, or tremors may occur followed by drowsiness, unconsciousness, and respiratory arrest.

Reactions involving the cardiovascular system include depression of the myocardium, hypotension, bradycardia, and possibly cardiac arrest.

The treatment of a patient with toxic manifestations consist of assuring and maintaining an open airway, and supporting adequate ventilation using oxygen and assisted or controlled respiration as required. This will be sufficient in most cases. Should circulatory depression occur, vasopressors such as Ephedrine or Metaraminol, and intravenous fluids may be used. Should a convulsion occur and persist despite oxygen therapy, small increments of an ultrashort acting barbiturate (thiopental or thiamylal) or a short acting barbiturate (pentobarbital or secobarbital) may be given intravenously. Intravenous barbiturates should only be used by those familiar with their use.

Allergic reactions are characterized by cutaneous lesions, urticaria, edema, or anaphylactoid reactions. The detection of sensitivity by skin tests is of doubtful value.

Persistent paresthesias of the lips, tongue, and oral tissues have been reported with the use of prilocaine, with slow, incomplete, or no recovery. These post-marketing events have been reported chiefly following nerve blocks in the mandible and have involved the trigeminal nerve and its branches.

DOSAGE AND ADMINISTRATION:

The dosage varies and depends on the area to be anaesthetized, vascularity of tissues, individual tolerance, and the technique used. The lowest dose needed to provide effective anaesthesia should be used. For specific techniques of local anaesthetic administration, consult standard textbooks on this subject.

For infiltration and nerve block injections in the upper or lower jaw, a dose of one cartridge will usually suffice. Each cartridge contains 1.8 mL of anaesthetic with 72 milligrams of Prilocaine.

The maximum dose for normal healthy adults is 600 mg (8mg/kg) or approximately 8 cartridges.

The maximum dosage for children should be calculated by using one of the standard pediatric drug formulas. Using Clark's rule for example for a child of 5 years weighing 23 kg, the dose of Prilocaine Hydrochloride should not exceed 150 mg (7mg/kg of body weight) or approximately 2 cartridges.

Any unused portion of a cartridge should be discarded. Do not sterilize cartridges with quaternary ammonium germicides as they react with the aluminum of the metal cap.

HOW SUPPLIED:

4% Citanest Forte with Epinephrine 1:200,000 is supplied in containers of 50 cartridges, each containing 1.8 mL of solution.