DIVERSE PATIENTS CALL FOR DIVERSE OPTIONS.

4% Citanest® Plain DENTAL (prilocaine HCl Injection, USP)
4% Citanest® Forte DENTAL with epinephrine 1:200,000 (prilocaine HCl and epinephrine injection, USP)

Citanest. For a wide spectrum of patient conditions.

Citanest, from DENTSPLY Pharmaceutical, gives patients more comfortable options for low-toxicity*, high-safety local anesthesia with Plain (no epinephrine) and Forte (with epinephrine). While both are safe for patients with a wide variety of medical conditions or circumstances, Plain offers pinchless, quick-on/quick-off while Forte works well for longer or extended procedures.

Citanest Plain and Citanest Forte are contraindicated in patients who are hypersensitive to local anesthetics. Citanest Plain and Citanest Forte should not be used in patients with congenital or idiopathic methemoglobinemia. Common precautions include aspiration prior to injection to help avoid intravascular injection. Local anesthetic solutions like Citanest Forte that contain a vasoconstrictor should be used cautiously especially in patients with impaired cardiovascular function or vascular disease.

Please refer to brief summary for prescribing information on adjacent page.

To learn more, call us at 1-800-225-2787 or visit dentsply.com.

Available in boxes of 50 cartridges of 1.8 ml with your local dealer. DENTSPLY part numbers are as below:

46616	4% Citanest Plain DENTAL (prilocaine HCl Injection, USP)
48816	4% Citanest Forte DENTAL with epinephrine 1:200,000 (prilocaine HCl and epinephrine injection, USP)

DENTSPLY PHARMACEUTICAL

Your trusted partner in dental anesthetics

*Stanley F. Malamed - Handbook of local anesthesia-6th Ed.

Citanest® Forte Dental

(prilocaine and epinephrine injection, USP) 4% Injection with epinephrine 1:200,000

4% Citanest Plain Dental

(prilocaine hydrochloride injection, USP)

BRIEF SUMMARY

[See Package Insert for Full Prescribing Information]

USE

Citanest© Forte Dental and 4% Citanest Plain Dental are indicated for the production of local anesthesia in dentistry by nerve block or infiltration techniques.

CONTRAINDICATIONS

Prilocaine is contraindicated in patients with known history of hypersensitivity to amide type local anesthetics and in patients with congenital or idiopathic methemoglobinemia.

WARNINGS

PRACTITIONERS WHO USE LOCAL ANESTHETICS SHOULD BE WELL VERSED IN DIAGNOSIS AND MANAGEMENT OF EMERGENCIES THAT MAY ARISE FROM THEIR USE. RESUSCITATIVE EQUIPMENT, OXYGEN AND OTHER RESUSCITATIVE DRUGS SHOULD BE AVAILABLE FOR IMMEDIATE USE. To minimize the likelihood of intravascular injection, aspiration should be performed before the local anesthetic is injected. If blood is aspirated, the needle must be repositioned until no blood can be elicited by aspiration. The absence of blood in the syringe does not assure that intravascular injection will be avoided.

Citanest Forte Dental Injection contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening asthmatic episodes. The overall presence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

Methemoglobinemia: Prilocaine has been associated with methemoglobinemia. Very young patients, patients with congenital or idiopathic methemoglobinemia, or patients with glucose-6-phosphate deficiencies are more susceptible. Patients taking drugs associated with methemoglobinemia (e.g., sulfonamides, acetaminophen, acetanilid, aniline dyes, benzocaine, chloroquine, dapsone, naphthalene, nitrates and nitrites, nitrofurantoin, nitroglycerin, nitroprusside, pamaquine, para-aminosalicylic acid, phenacetin, phenobarbital, phenytoin, primaquine and quinine) are at greater risk.

PRECAUTIONS

General: Prilocaine's safety and effectiveness depend on proper dosage, correct technique, adequate precautions, and readiness for emergencies. Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use (see **WARNINGS**). The lowest dosage that results in effective anesthesia should be used to avoid high plasma levels and serious adverse effects. Repeated doses of prilocaine may cause significant increases in blood levels with each repeated dose because of slow accumulation of the drug or its metabolites. Tolerance to elevated blood levels varies with the status of the patient. Patients that are debilitated, elderly, acutely ill, and children should be given reduced doses commensurate with age and physical status. Prilocaine should be used with caution in those with severe shock or heart block.

Local anesthetic injections containing a vasoconstrictor should be used cautiously in areas of the body supplied by end arteries or having otherwise compromised blood supply. Patients with peripheral vascular disease and those with hypertensive vascular disease may exhibit exaggerated vasoconstrictor response. Ischemic injury or necrosis may result. Preparations containing a vasoconstrictor (Citanest© Forte Dental) should be used with caution during or after administration of potent general anesthetics, since cardiac arrhythmias may occur.

Cardiovascular and respiratory (adequacy of ventilation) vital signs and the patient's state of consciousness should be monitored after each local anesthetic injection. Restlessness, anxiety, tinnitus, dizziness, blurred vision, tremors, depression or drowsiness should alert the practitioner to the possibility of central nervous system toxicity. Signs and symptoms of depressed cardiovascular function may result from a vasovagal reaction; particularly if the patient is in an upright position (see **ADVERSE REACTIONS, Cardiovascular System**).

Since amide-type local anesthetics are metabolized by the liver, prilocaine should be used with caution in patients with hepatic disease. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at greater risk of developing toxic plasma concentrations. Prilocaine should be used with caution in patients with impaired cardiovascular function since they may be less able to compensate for functional changes associated with the prolongation of A-V conduction produced by these drugs.

Many drugs used during the conduct of anesthesia are potential triggering agents for familial malignant hyperthermia. Since it is not known whether amide-type local anesthetics may trigger this reaction and since the need for supplemental anesthesia cannot be predicted in advance, it is suggested that a standard protocol for the management of malignant hyperthermia should be available. Early unexplained signs of tachycardia, tachypnea, labile blood pressure and metabolic acidosis may precede temperature elevation. Outcome success is dependent on early diagnosis, prompt discontinuance of the suspect triggering agent(s) and institution of treatment, including oxygen therapy, indicated supportive measures and dantrolene (consult dantrolene sodium intravenous package insert before using).

Prilocaine should be used with caution in patients with known drug sensitivities. Patients allergic to para-aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to prilocaine.

Use in the Head and Neck Area: Small doses of local anesthetics injected into the head and neck area, including retrobulbar, dental and stellate ganglion blocks, may produce adverse reactions similar to systemic toxicity seen with unintentional intravascular injections of larger doses. Confusion, convulsions, respiratory depression and/or respiratory arrest, and cardiovascular stimulation or depression have been reported. These reactions may be due to intra-arterial injection of the local anesthetic with retrograde flow to the cerebral circulation. Patients receiving these blocks should have their circulation and respiration monitored and be constantly observed. Personnel for treating adverse reactions should be immediately available. Dosage recommendations should not be exceeded (see **DOSAGE AND ADMINISTRATION** in package insert).

Information for Patients: The patient should be informed of the possibility of temporary loss of sensation and muscle function after infiltration or nerve block injections. The patient should be advised to exert caution to avoid inadvertent trauma to the lips, tongue, cheek mucosae or soft palate when these structures are anesthetized. The ingestion of food should therefore be postponed until normal function returns. The patient should be advised to consult the dentist if anesthesia persists, or if a rash develops.

Clinically Significant Drug Interactions: The administration of local anesthetic injections containing epinephrine or norepinephrine in patients receiving monoamine oxidase inhibitors, tricyclic antidepressants or phenothiazines may produce severe, prolonged hypotension or hypertension. Concurrent use of these drugs should generally be avoided. In situations when concurrent therapy is necessary, careful patient monitoring is essential. Concurrent administration of vasopressor and ergot-type oxytocic drugs may cause severe, persistent hypertension or cerebrovascular accidents. Prilocaine may contribute to the formation of methemoglobinemia in patients treated with other drugs known to cause this condition (see **WARNINGS**).

Drug/Laboratory Test Interactions: Intramuscular injection of prilocaine may result in increased creatine phosphokinase levels. Thus, the use of this enzyme determination, without isoenzyme separation, as a diagnostic test for the presence of acute myocardial infarction may be compromised by the intramuscular injection of prilocaine.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies of prilocaine in animals to evaluate the carcinogenic and mutagenic potential or the effect on fertility have not been conducted. Chronic oral toxicity studies of ortho-toluidine, a prilocaine metabolite, in mice (150–4800 mg/kg) and rats (150–800 mg/kg) have shown that ortho-toluidine is a carcinogen in both species. The lowest dose corresponds to approximately 50 times the maximum amount of ortho-toluidine to which a 50 kg subject would be expected to be exposed following a single injection (3 mg/kg) of prilocaine. Ortho-toluidine (0.5 mg/mL) showed positive results in *Escherichia coli* DNA repair and phage-induction assays. Urine concentrates from rats treated with ortho-toluidine (300 mg/kg, orally) were mutagenic for *Salmonella typhimurium* with metabolic activation. Several other tests, including reverse mutations in five different *Salmonella typhimurium* strains with or without metabolic activation and single strand breaks in DNA or V79 Chinese hamster cells, were negative.

Use in Pregnancy: *Teratogenic Effects* — Pregnancy Category B.Reproduction studies have been performed in rats at doses up to 30 times the human dose and revealed no evidence of impaired fertility or harm to the fetus due to prilocaine. There are, however, no adequate and well-controlled studies in pregnant women. Animal reproduction studies are not always predictive of human response. General consideration should be given to this fact before administering prilocaine to women of childbearing potential, especially during early pregnancy when maximum organogenesis takes place.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when prilocaine is administered to a nursing woman.

Pediatric Use: Dosages in children should be reduced, commensurate with age, body weight, and physical condition (see **DOSAGE AND ADMINISTRATION** in package insert).

ADVERSE REACTIONS

Swelling and persistent paresthesia of lips and oral tissues may occur. There have been reports of persistent paresthesia lasting weeks to months, and in rare instances paresthesia lasting greater than one year. Adverse experiences after prilocaine administration are similar to those observed with other amide local anesthetics. These adverse experiences are generally dose-related and may result from high plasma levels caused by excessive dosage, rapid absorption or unintentional intravascular injection, or may result from patient hypersensitivity, idiosyncrasy or diminished tolerance. Serious adverse experiences are generally systemic in nature. The following types are those most commonly reported:

Central Nervous System: CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression, and arrest. Excitatory manifestations may be brief or may not occur at all. The first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest. Drowsiness after administration of prilocaine is usually an early sign of a high blood level of the drug and may occur as a consequence of rapid absorption.

Cardiovascular System: Cardiovascular manifestations are usually depressant and characterized by bradycardia, hypotension and cardiovascular collapse, which may lead to cardiac arrest. Signs and symptoms of depressed cardiovascular function may commonly result from a vasovagal reaction, particularly if the patient is upright. Less commonly, they may result from a direct effect of the drug. Failure to recognize the premonitory signs (e.g., sweating, a feeling of faintness, changes in pulse or sensorium) may result in progressive cerebral hypoxia and seizure or cardiovascular catastrophe. Management consists of placing the patient in the recumbent position and ventilation with oxygen. Supportive treatment of circulatory depression may require administration of intravenous fluids, and, when appropriate, a vasopressor (e.g., ephedrine) as directed by the clinical situation.

Allergic: Allergic reactions are characterized by cutaneous lesions, urticaria, edema or anaphylactoid reactions. Allergic reactions as a result of sensitivity to prilocaine are extremely rare and, if they occur, should be managed by conventional means.

Neurologic: Adverse reactions (e.g., persistent neurologic deficit) associated with the use of local anesthetics may be related to the technique used, the total dose administered, the particular drug, the route of administration, and the physical condition of the patient.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at http://www.fda.gov/Safety/MedWatch/default.htm or call 1-800-FDA-1088.

OVERDOSAGE Acute emergencies from local anesthetics are generally related to high plasma levels encountered during therapeutic use of local anesthetics (see **WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS**).

Management of Local Anesthetic Emergencies: The first consideration is prevention, best accomplished by careful and constant monitoring of cardiovascular and respiratory vital signs and state of consciousness after each local anesthetic injection. At the first sign of change, oxygen should be administered. The first step in the management of convulsions is immediately attending to the maintenance of a patent airway and assisted or controlled ventilation with oxygen and a delivery system capable of permitting immediate positive airway pressure by mask. Immediately after the institution of these ventilatory measures, the adequacy of the circulation should be evaluated. Should convulsions persist despite adequate respiratory support, and if the status of the circulation permits, small increments of an ultra-short acting barbiturate (e.g., thiopental or thiamylal) or a benzodiazepine (e.g., diazepam) may be administered intravenously. The clinician should be familiar with these anticonvulsant drugs. Supportive treatment of circulatory depression may require intravenous fluids and, when appropriate, a vasopressor as directed by the clinical situation (e.g., ephedrine). If not treated immediately, both convulsions and cardiovascular depression can result in hypoxia, acidosis, bradycardia, arrhythmias and cardiac arrest. If cardiac arrest occurs, standard cardiopulmonary resuscitative measures should be instituted. Endotracheal intubation, employing drugs and techniques familiar to the clinician, may be indicated, after initial administration of oxygen by mask, if difficulty is encountered in the maintenance of a patent airway or if prolonged ventilatory support (assisted or controlled) is indicated. Dialysis is of negligible value in the treatment of acute overdosage with prilocaine. Methemoglobinemia is generally dose related but may occur at any dose. While values of less than 20% do not tend to produce any clinical symptoms, cyanosis at 2–4 hours after administration should be evaluated in terms of the patient's general health status. Methemoglobinemia can be reversed when indicated by intravenous methylene blue at a dosage of 1–2 mg/kg given over five minutes.

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