INDICATIONS AND USAGE
LIDOCAINE HCl 3% is an amide-type Local Anesthetic indicated for:
Relief of pain at one or more sites in the mouth, including dental pain; pain from neuroma, local medical procedures, injections and vaccines; relief of pruritus, pruritic eczema, abrasions, minor burns, insect bites, poison, urticaria, and discomfort due to pruritus
CONTACTS
Therapeutic system for secondary bacterial infection of the areas proposed and application of LIDOCAINE HCl 3% to any of the areas.

WARNING AND PRECAUTIONS
For External Use Only. Avoid contact with eyes. If contact with eyes occurs, discontinue use and institute appropriate therapy.

LIDOCAINE HCl 3% should be used with caution in elderly, debilitated patients and children because they may be more sensitive to the systemic effects of Local Anesthetics.

Reactions of Methemoglobinemia: Patients should be warned that methemoglobinemia, characterized by a bluish discoloration of the skin and mucous membranes, may occur when local anesthetics containing amphetamines are used to facilitate surgery in patients with thalassemia or G6PD deficiency. Methemoglobinemia may also occur in patients with no apparent pre-existing hemoglobinopathy if the mother is administered local anesthetics may be at increased risk of developing methemoglobinemia when concurrently exposed to the following oxidizing agents: nitrofurantoin, nitrofurazone, nitroglycerin, nitrate, nitric oxide, sodium nitrate, sodium nitrate, sodium thiosulfate, Dofetilide, Imitapride, Beta-blockers (eg, Luminitel, Bupivacaine, Lidocaine, Lidocaine, bupivacaine, epinephrine, tericline, procaine, atropine, ropivacaine), Anthelphins (epinephrine, phenylephrine), non-steroidal anti-inflammatory drugs (NSAIDs), or vehicle lowers pH to increase protection against alkaline irritations and to provide a favorable environment for healing.

3. Dosage Form and Strength:
2.2 Administration:
3.2 Methemoglobinemia:
3.2.1 Identifying the patient:
3.2.2 Treatment:

DOSAGE IN CHILDREN
Dosage in children should be reduced, commensurate with age, body weight and physical condition. Geriatric use:

TERATOGENIC EFFECTS - Pregnancy Category B.

METHODS OF ADMINISTRATION
3% (Lidocaine HCl USP 3%) should be administered in any one day. Although the incidence of adverse effects with LIDOCAINE HCl 3% is quite low, caution should be exercised particularly in patients with impaired renal function, when LIDOCAINE HCl 3% is to be used near a nerve trunk or to a single large muscle mass, or when given with other agents that cause methemoglobinemia (eg, nitrites, nitrates, or amphetamines). The dose of LIDOCAINE HCl 3% should never exceed 180 mg (5.6 mg/kg) of Lidocaine Hydrochloride USP per dose in any one day.

LIDOCAINE HCl 3% is generally for use on the skin only. If your medication comes with patient instructions for safe and appropriate use, please follow these instructions. The medication should be applied only to the outside skin areas. Do not use LiDORx 

Ineffective Ingredients:
10.2 Inactive Ingredients:

Ineffective Ingredients:

Use exactly as prescribed by your doctor. Do not use in larger or smaller amounts or for longer than recommended. Follow the directions on your prescription label. LIDOCAINE HCl 3% is for use on the skin only.

The patient’s condition should be closely observed for at least 30 minutes after the injection to detect signs of anaphylactic reaction. If anaphylactic reaction occurs during its use, discontinue use and institute appropriate therapy immediately.

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If local anesthetics must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended. Signs and symptoms of methemoglobinemia may occur immediately or may be delayed some hours after exposure and are characterized by a cyanotic skin discoloration and abnormal coloration of the blood. Methemoglobin levels may continue to rise; therefore, immediate attention to the maintenance of a patent airway and assisted or controlled ventilation with oxygen and a cylinder of carbon dioxide, a 10% solution of sodium bicarbonate, or methemoglobin reductase, such as methylene blue, should be performed. A high percentage of methemoglobin, as demonstrated by a change in the reddish-purple color of the blood to a dark brown color, is likely to result in death. Contact your doctor at once if you have any of these serious side effects:

8 USE IN SPECIFIC POPULATIONS 8.1 Pregnancy 8.2 Labor and Delivery 8.3 Nursing Mothers 8.4 Pediatric Use 8.5 Geriatric Use

9 OVERDOSAGE
9.1 Symptoms
9.2 Treatment

OVERDOSE
Overdose symptoms may include drowsiness, confusion, nervousness, ringing in your ears, blurred vision, feeling hot or cold, numbness, muscle twitches, absence or hypertension, and respiratory depression. An antidote for LIDOCAINE HCl 3% is generally for use on the skin only. If your medication comes with patient instructions for safe and appropriate use, please follow these instructions. The medication should be applied only to the outside skin areas. Do not use LiDORx 

If you forget to take a dose, take it as soon as you remember it. If it is almost time for your next dose, skip the missed dose and take your next dose at the regular time. Do not take a double dose to make up for a missed one.

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The patient’s condition should be closely observed for at least 30 minutes after the injection to detect signs of anaphylactic reaction. If anaphylactic reaction occurs during its use, discontinue use and institute appropriate therapy immediately.

2.1 Developmental and Growth:
2.2 Administration:

11 CLINICAL PHARMACOLOGY 11.1 Mechanism of Action 11.2 Duration and Axiology of Action 11.3 Hemodynamics 11.4 Pharmacokinetics and metabolism 11.5 CLINICAL USE (LIDOCAINE HCl 3%)

1. Indications:

7.8 Other Special Populations: The pharmacokinetics of LIDOCAINE HCl 3% have been evaluated in patients with hepatic insufficiency (Child-Pugh Class A and B) and renal insufficiency (creatinine clearance 10 to 100 mL/min). In patients with hepatic insufficiency, LIDOCAINE HCl 3% is usually well tolerated. In patients with renal insufficiency, an increase in the serum concentration of Lidocaine Hydrochloride USP occurs, possibly due to decreased metabolism in this population. While the serum concentration of Lidocaine Hydrochloride USP is increased, the elimination half-life is similar to that in normal volunteers. Therefore, the usual dosage regimen should not be altered in patients with renal insufficiency.

11.2 Mechanism of action:

11.1 Mechanism of Action:

In patients with hepatic insufficiency, it is recommended that the dosing interval be increased, commensurate with age, body weight and physical condition. Caution must be taken to avoid overdosing when applying LIDOCAINE HCl 3% in large areas of injured or abraded skin, since the systemic absorption of LIDOCAINE HCl USP may be increased under such conditions.

8.1 Use in Specific Populations: Therapeutic effects: LIDOCAINE HCl 3% is used to provide local anesthesia at one or more sites in the mouth. LIDOCAINE HCl 3% is applied as needed, you may not be on a dosing schedule. If you are using the medication regularly, use the missed dose as soon as you remember it. Do not use extra medicine to make up for the missed one.