Prilox*

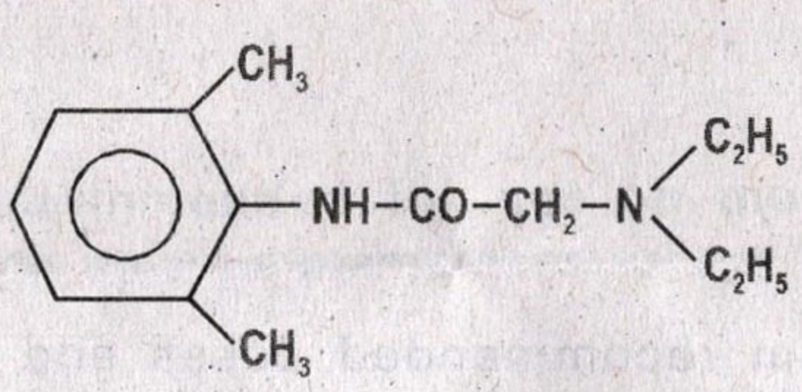
For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

(Lidocaine and Prilocaine Cream USP)

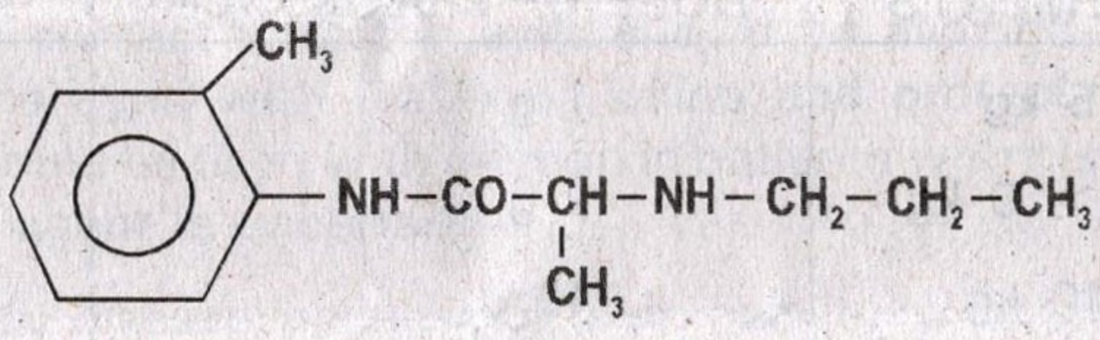
DESCRIPTION:

Prilox Cream (Lidocaine and Prilocaine Cream USP) is an emulsion in which oil phase is a eutectic mixture of lidocaine and prilocaine in a ratio of 1:1 by weight. This eutectic mixture has a melting point below the room temperature and therefore both local anaesthetics exist as liquid oil rather than as crystals.

Lidocaine is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl), has an octonol water partition ratio of 43 at pH 7.4 and has the following structure:



Prilocaine is chemically designated as propanamide, N-(2-methylphenyl)-2-(propylamino), has an octonol water partition ratio of 25 at pH 7.4 and has the following structure:



COMPOSITION:

Each gram of **PRILOX** contains Lidocaine USP 25 mg, Prilocaine USP 25 mg.

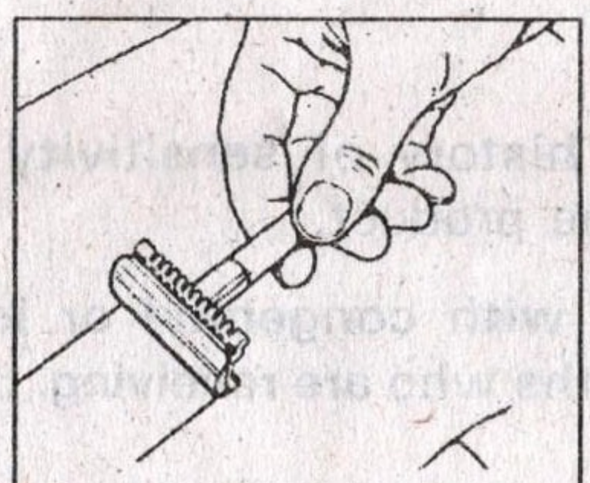
CLINICAL PHARMACOLOGY:

Mechanism of action: PRILOX Cream (Lidocaine and Prilocaine Cream USP), when applied to intact skin under occlusive dressing, provides dermal analgesia by the release of lidocaine and prilocaine from the cream into the epidermal and dermal layers of the skin, leading to accumulation of lidocaine and prilocaine in the vicinity of dermal pain receptors and nerve endings. Both Lidocaine and Prilocaine stabilize the neuronal membranes by inhibiting the ionic fluxes required for initiation and conduction of impulses, thereby resulting in local anaesthetic action.

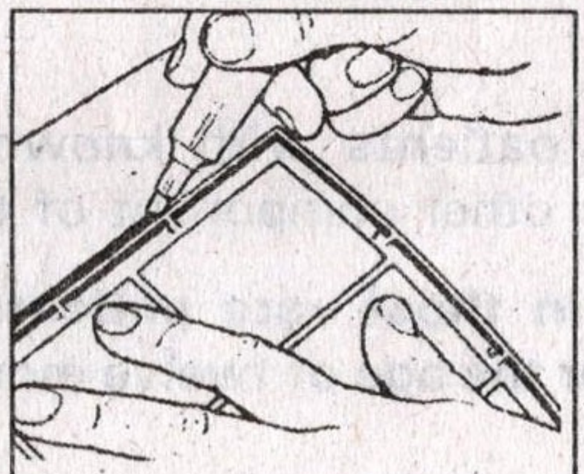
INDICATIONS:

PRILOX Cream (Lidocaine and Prilocaine Cream USP) is indicated as a topical anaesthetic for use on normal **intact skin only,** for local analgesia, for the following procedures:

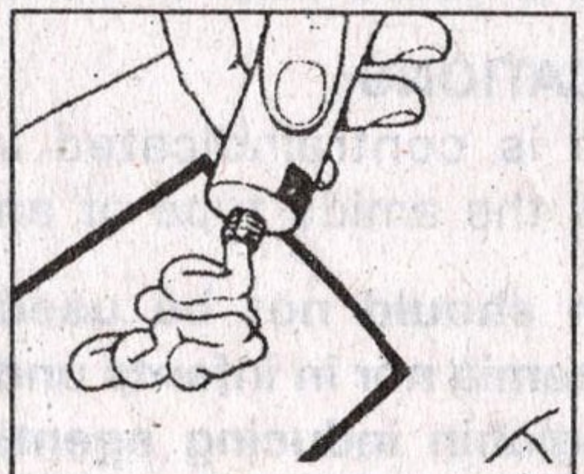
Prilox application



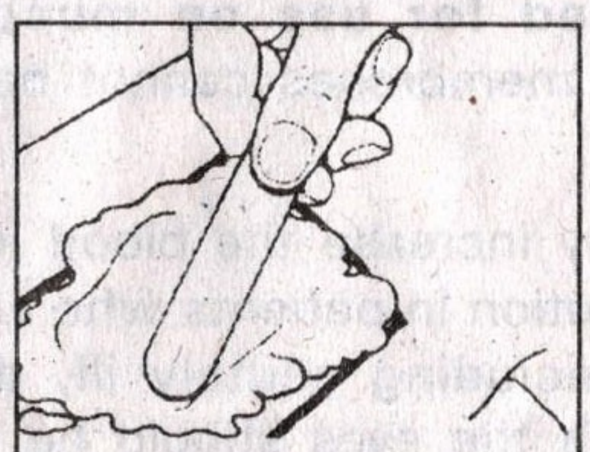
1 Shave the skin of the selected site. Clean the area with alcohol.



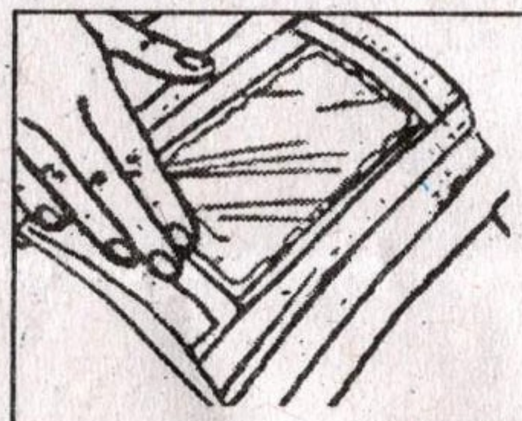
2 Select the exact site and mark this area using indelible thick marker pen to delineate the margins of the site.



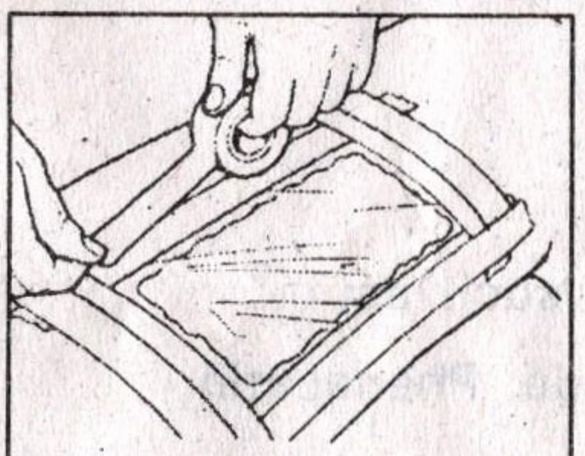
3 Squeeze out Cream from PRILOX tube on the area to be anaesthetised.



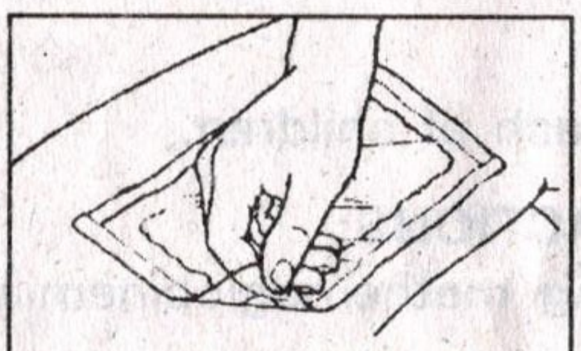
4 Spread PRILOX Cream using a spatula to form a thick even layer of 2-3mm. It is important to completely cover entire area including the marked margins of the site



5 Take a strip of occlusive dressing, cut to the appropriate size (slightly larger than the area of the site). Carefully apply the occlusive dressing to completely cover the layer of PRILOX Cream. Do not compress.



6 Smooth down and tape the edges of the occlusive dressing to the skin using a surgical synthetic adhesive tape. Leave PRILOX Cream with occlusive dressing for minimum 1-2 hrs, as per the need. As a reminder, the time can be written near the site with a marker pen



7 Just prior to surgery, remove the occlusive dressing and wipe off PRILOX Cream. Disinfect and prepare the anaesthetised site for surgery.

including CNS excitation and/or depression (light headedness, nervousness, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat or cold or numbness, twitching, tremors, convulsion, unconsciousness, respiratory depression and arrest). Excitatory CNS reactions may be brief or may not occur at all, in which case the first manifestation may be drowsiness merging into unconsciousness. Cardiovascular manifestation may include bradycardia, hypotension and cardiovascular collapse leading to arrest.

OVERDOSAGE:

Toxic levels of lidocaine (>5µg/ml) and / or Prilocaine (>6µg/ml) cause a decrease in cardiac output, total peripheral resistance and mean arterial pressure. These changes may be attributed to the direct depressant effects of these local anaesthetic agents on the cardiovascular system. In the absence of massive topical overdose or oral ingestion, evaluation should include evaluation of other etiologies for the clinical effects or overdosage from other sources of lidocaine, prilocaine or other local anaesthetics.

STORAGE:

Keep the tube tightly closed at all times when not in use. Store in a dry place, below 30°C., protected from light. Do not Freeze.

APPLICATION:

It is very important to follow exactly the instructions given below:

1. Squeeze the appropriate quantity (refer to dosage instructions) of the cream into a mound on the site, spread the cream with the help of spatula to form a thick even layer of 2-3 mm.
   DO NOT RUB THE CREAM IN.
2. Carefully cover the layer of PRILOX Cream with occlusive dressing and do not compress the cream under the dressing.
3. Smooth down the edges of the occlusive dressing to the skin, using a surgical adhesive tape. Leave PRILOX Cream with occlusive dressing for minimum 1-2 hrs, as per the need.
4. Before the medical procedure, remove the dressing and then sterilize that area. No sterilization is required before application of the Cream.

PRESENTATION:

PRILOX Cream is supplied as 5 gm and 30 gm tube. Each gram of Prilox contains Lidocaine USP 25 mg and Prilocaine USP 25 mg in Water-Miscible base.

MADE IN INDIA BY:
NEON LABORATORIES LIMITED
28, Mahal Ind. Est., M. Caves Rd.,
Andheri (East), Mumbai - 400 093.

P279

Other drugs / chemicals: Aniline dyes, Naphthalene, Para-aminosalicylic acid.

PRILOX Cream should be used with caution in patient receiving class I antiarrhythmic drugs (such tocainide and mexiletine), since the toxic effects are additive and potentially synergistic.

WARNING:

Application of PRILOX Cream to larger areas or for longer durations than those recommended could result in sufficient absorption of lidocaine and prilocaine resulting in serious adverse effects.

USE IN PREGNANCY:

Reproductive studies conducted in rats with Lidocaine and Prilocaine have revealed no evidence of impaired fertility or harm to the fetus. However, since there are no adequate or well controlled studies in pregnant women, PRILOX Cream should be used in pregnancy only if clearly needed.

USE IN LABOR AND DELIVERY:

Neither lidocaine nor prilocaine are contraindicated in labor and delivery. Should PRILOX Cream be used concomitantly with other products containing lidocaine and/or prilocaine, total dose contributed by all the formulation must be considered.

NURSING MOTHERS:

Lidocaine and probably prilocaine, are excreted in human milk. Hence, caution should be exercised.

PEDIATRIC USE:

PRILOX Cream should be used with care in patients taking therapy associated with methemoglobinemia. While using PRILOX Cream in young children, especially infants under the age of three months, care must be taken to limit the area and dose of application, and to prevent ingestion.

In children above one month of age weighing less than 20 kg, the area and duration of application should be limited.

SIDE EFFECTS:

Localized Reaction: During or immediately after treatment with PRILOX Cream, the skin at the site of treatment may develop erythema or edema or may be the locus of abnormal sensation. Rare cases of hyperpigmentation following the use of PRILOX Cream have been reported.

Allergic Reaction: Allergic and anaphylactic reactions associated with lidocaine and prilocaine can occur. They are characterized by urticaria, angioedema, bronchospasm and shock. If they occur, they should be managed by conventional means.

Systemic (Dose Related) Reactions: Systemic adverse reactions following appropriate use of PRILOX Cream are unlikely due to the small dose absorbed. Systemic adverse effects of lidocaine and/or prilocaine are similar to those of other amide type of local anaesthetic agents

Dermal analgesia can be expected to increase for upto 3 hrs. under occlusive dressing and persist for 1 to 2 hours after removal of the cream.

CONTRAINDICATIONS:

PRILOX Cream is contraindicated in patients with known history of sensitivity to local anaesthetics of the amide type or any other component of the product.

PRILOX Cream should not be used in those rare patients with congenital or idiopathic methemoglobinemia nor in infants under the age of twelve months who are receiving treatment with methemoglobin inducing agents.

PRILOX Cream is not recommended in any clinical situation, in which penetration or migration beyond the tympanic membrane into the middle ear is possible because of the ototoxic effect observed in animal studies.

PRECAUTIONS:

PRILOX Cream is not recommended for use on mucous membranes. Safe dosing recommendations for use on mucous membranes cannot be made because it has not been studied adequately.

Repeated doses of PRILOX Cream may increase the blood level of lidocaine and prilocaine. PRILOX Cream should be used with caution in patients who are more sensitive to the systemic effects of prilocaine and lidocaine including acutely ill, debilitated and elderly patients. PRILOX Cream coming in contact with the eyes should be avoided. If eye contact occurs, immediately wash out the eyes with water or saline and protect the eye until sensation returns. PRILOX Cream should be used with caution in patients with history of drug sensitivities, especially if the etiologic agent is uncertain.

Patients with severe hepatic disease, because of their inability to metabolise local anaesthetics, normally are at a greater risk of developing toxic plasma concentration of lidocaine and prilocaine.

Keep out of reach of children.

DRUG INTERACTIONS:

Agents inducing methemoglobinemia, such as:

Analgesics: Acetaminophen, Acetanilide, Phenacetin

Anaesthetics: Benzocaine

Anticonvulsants: Phenobarbital, Phenytoin

Antimalarial Agents: Chloroquine, Pamaquine, Primaquine, Quinine

Sulfonamides / sulfones: Dapsone, Sulfamethoxazole, Trimethoprim

Nitrates: Nitrates and nitrites, Nitrofurantoin, Nitroglycerin, Nitroprusside

- Split skin graft harvesting
- Superficial skin surgeries
- Superficial biopsy
- Removal of Molluscum bodies & tattoos
- Electrosurgery of Cutaneous lesions
- Treatment of Condylomata acuminata
- Electrocoagulation
- Premedication for Lignocaine infiltration before skin biopsy.
- Venipuncture
- Intravenous Cannulation

DOSAGE & ADMINISTRATION:

PEDIATRIC PATIENTS:

The following are the maximum recommended doses and areas of application for PRILOX Cream, based on a child's age and weight.

AGE & BODY WEIGHT REQUIREMENTS	MAXIMUM TOTAL DOSE OF PRILOX Cream	MAXIMUM APPLICATION AREA
1-3 months or < 5 kg	1 g	10 sq. cm.
4-12 months and > 5 kg	2 g	20 sq. cm.
1-6 years and > 10 kg	10 g	100 sq. cm.
7-12 years and > 20 kg	20 g	200 sq. cm.

Please note: If a patient more than 3 months old does not meet the minimum weight requirements, the maximum total dose of Eutectic mixture of lidocaine and prilocaine should be restricted to that which corresponds to the patient's weight.

Care should be taken to prevent accidental ingestion of Eutectic mixture of lidocaine and prilocaine.

PRILOX Cream should not be used in infants under the age of one month nor in infants under the age of twelve months who are receiving treatment with methemoglobinemia- inducing agents.

ADULT PATIENTS:

A 2 to 3 mm thick layer (approximately 2gm per 10sq cm) of Prilox Cream to be applied on the intact skin under occlusive dressing for 1 to 2 hours.