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

TOPLAP GEL

1. **Generic Name**

   Lidocaine and Prilocaine Gel

2. **Qualitative and quantitative composition**

   Lidocaine IP……..2.50% w/w

   Prilocaine IP……..2.50% w/w

   In a Gel Base

3. **Dosage form and strength**

   Dosage form: Gel

   Strength: Lidocaine 2.50 % w/w and Prilocaine 2.50 % w/w

4. **Clinical particulars**

4.1 Therapeutic indication

It is indicated for the treatment of as a topical and aesthetic for use on normal intact skin for local anaesthesia.

4.2 Posology and method of administration.

Age	Body Weight	Maximum total dose	Maximum area of application
1-3 months	<5 kg	1 g	10 cm^2
4-12 months	5-10 kg	2 g	20 cm^2
1-6 years	>10 kg	10 g	100 cm^2
7-12 years	>20 kg	20 g	200 cm^2

TOPLAP Gel 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 agent

ADULT PATIENTS:

1 TO 2G for 10 cm2 for TOPLAP Gel to be applied on the intact skin under occlusive dressing for 1 to 2 hrs. Inadequate application results in inadequate analgesia

HOW TO APPLY TOPLAP Gel

Squeeze the appropriate quantity of the Gel into a mound on the site, spread the Gel with help of Spatula to form a thick even layer of 2-3 mm height. DO NOT RUB THE GEL IN.

Take an Occlusive dressing which has been provided and cut to the appropriate size (adequately larger than the area of the site). Carefully remove the release liner of the Occlusive dressing so as to expose the adhesive

Apply the dressing to completely cover the layer of TOPLAP Gel Press down only along the edges so that the adhesive dressing edges stick to skin. Leave TOPLAP Gel with the Occlusive dressing for minimum 1-2 hrs, as per the need.

4.3 Contraindications

TOPLAP Gel is contraindicated in patients with known history of sensitivity to Lidocaine, Prilocaine and any other component of the product.

TOPLAP Gel 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 agent. Application of TOPLAP Gel is contraindicated in any clinical situation in which its migration into the middle ear is possible.

4.4 Special warnings and precautions for use

The use of TOPLAP Gel in the areas close to the eyes should be exercised with caution. If eye contact occurs, immediately wash out the eyes with water or saline and protect the eye until sensation returns.

Repeated doses may increase blood levels of Prilocaine and Lidocaine. TOPLAP Gel 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

4.5 Drugs interactions

Agents inducing Methemoglobinemia, such as:

Analgesic:

Acetaminophen, Acetanilide, Phenacetin

Anaesthetic:

Benzocaine

Anticonvulsants:

Phenobarbital, Phenytoin

Antimalarial Agents:

Chloroquine, Pamaquine, Primaquine, Quinine

Sulfonamides/Sulfones:

Dapsones, Sulfamethoxazole, Trimethoprim

Nitrates:

Nitrate and Nitrites, Nitrofurantoin, Nitroglycerine, Nitrofrusside.

Other Drugs/Chemicals:

Aniline dyes, Naphthalene, Para-aminosalicylic Acid.

TOPLAP Gel should be used with caution in patient receiving class I antiarrhythmic drugs (such as Tocainide & Mexiletine), since the toxic effect are additive and potentially synergistic

4.6 Use in special populations (Such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Since there are no adequate and well controlled studies in pregnant women, TOPLAP GEL should be used in pregnancy only if benefits outweighs the risk.

Use in Labor and Delivery

Neither Lidocaine nor Prilocaine are contraindicated in labor and delivery. If TOPLAP GEL should be used along with other products containing Lidocaine and/or Prilocaine, total dose contributed by all the formulation must be considered.

Nursing Mothers:

Lidocaine and Prilocaine are probably excreted in human milk. Caution to be exercised

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects:

Allergic and anaphylactic reactions associated with Lidocaine and Prilocaine can occur. They are charecterize3d by urticarial, angioedema, bronchospasm and shock. If they occur, they should be managed by conventional means.

During or immediately after treatment with TOPLAP GEL 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 TOPLAP GEL have been reported.

Systemic adverse reactions following appropriate use of TOPLAP GEL are unlikely due to the small dose absorbed. Systemic adverse effects of Lidocaine and Prilocaine are similar to those of other Amide type of local anaesthetic agents including CNS excitation and depression (light headedness, nervousness, euphoria, dizziness, drowsiness, blurred of double vision, vomiting and sensation of heat or cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest). Cardiovascular manifestation may include bradycardia, hypotension and cardiovascular collapse leading to arrest.

Reporting of suspected adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: https://www.torrentpharma.com/index.php/site/info/adverse_event_reporting

4.9 Overdose

Not applicable

5. Pharmacological properties

5.1 Mechanism of Action

TOPLAP GEL when applied to intact skin under occlusive dressing, provides dermal analgesia by the release of Lidocaine and Prilocaine from the Gel into the epidermal and dermal layers of the skin, leading to accumulation of active ingredients in the vicinity of the dermal pain receptors and nerve endings. Both the active ingredients stabilize the neuronal membranes by inhibiting the ionic fluxes required for initiation and conduction of impulses, thereby resulting in local anaesthetic action.

5.2 Pharmacodynamic properties

Not applicable

5.3 Pharmacokinetic properties

Not applicable

6. Nonclinical properties

Not applicable

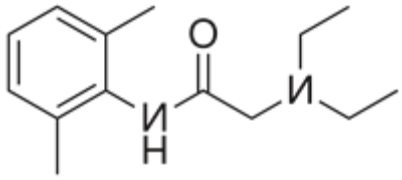
6.1 Animal Toxicology or Pharmacology

Not applicable

7. Description

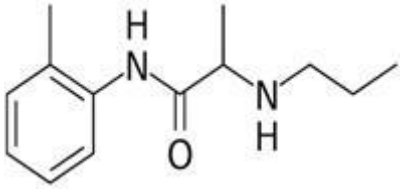
Lidocaine:

Lignocaine is acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-; 2-(Diethylamino)-2'6'-acetoxylidide.The empirical formula is $C_{14}H_{22}N_2O$ and its molecular weight is 234.3g/mol. The chemical structural formula is:



Prilocaine:

Prilocaine is propanamide, N-(2- methylphenyl)-2-(propylamino); 2-(Propylamino)-o-propinotoluidide; (RS)-N-(2-methylphenyl)-2-(propylamino) propanamide. The empirical formula is $C_{13}H_{20}N_2O$ and its molecular weight is 220.3 g/mol. The chemical structural formula is:



Toplap Gel:

Lidocaine and Prilocaine Gel are a white, smooth, homogenous gel free from foreign particles. The excipients used are Carbopol Ultrez, Cresmer RH, Butylated Hydroxy Toluene, Methyl Paraben, Sodium Hydroxide.

8. Pharmaceutical particulars

8.1 Incompatibilities

None known.

8.2 Shelf-life

Do not use later than date of expiry

8.3 Packaging information

TOPLAP GEL is available in pack of 10 gm and 30 gm.

8.4 Storage and handing instructions

Do not store above 30°C. Do not freeze.

Do not apply near eyes or on open wounds.

Do not use in children under one month of age.

Keep out of reach of children.

9. Patient Counselling Information

TOPLAP GEL

(Lidocaine and Prilocaine Gel)

Read all of this leaflet carefully before you start taking this medicine because it contains Important information for you.

· Keep this leaflet. You may need to read it again.

· If you have any further questions, ask your doctor or pharmacist.

· This medicine has been prescribed for you only. Do not pass it on to others; it may harm them, even if their signs of illness are the same as yours.

· If you get any side effects, talk to your doctor or pharmacist. This includes any possible side Effects not listed in this leaflet.

What is in this leaflet?

9.1 What TOPLAP GEL is and what it is used for

TOPLAP GEL contain Lidocaine and Prilocaine Gel.

It is indicated for the treatment of as a topical and aesthetic for use on normal intact skin for local anaesthesia

9.2 What you need to know before you take TOPLAP GEL

Do not take TOPLAP GEL if:

If you are allergic to Lidocaine and Prilocaine.

Special warnings and precautions for use

The use of TOPLAP Gel in the areas close to the eyes should be exercised with caution. If eye contact occurs, immediately wash out the eyes with water or saline and protect the eye until sensation returns.

Repeated doses may increase blood levels of Prilocaine and Lidocaine. TOPLAP Gel 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

9.3 How to apply TOPLAP GEL.

Squeeze the appropriate quantity of the Gel into a mound on the site, spread the Gel with help of Spatula to form a thick even layer of 2-3 mm height. DO NOT RUB THE GEL IN.

Take an Occlusive dressing which has been provided and cut to the appropriate size (adequately larger than the area of the site). Carefully remove the release liner of the Occlusive dressing so as to expose the adhesive

Apply the dressing to completely cover the layer of TOPLAP Gel Press down only along the edges so that the adhesive dressing edges stick to skin. Leave TOPLAP Gel with the Occlusive dressing for minimum 1-2 hrs, as per the need.

9.4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic and anaphylactic reactions associated with Lidocaine and Prilocaine can occur. They are charecterize3d by urticarial, angioedema, bronchospasm and shock. If they occur, they should be managed by conventional means.

During or immediately after treatment with TOPLAP GEL 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 TOPLAP GEL have been reported.

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9.5 How to store TOPLAP GEL.

Do not store above 30°C. Do not freeze.

9.6 Contents of the pack and other information

TOPLAP GEL Consists of Lidocaine I.P and Prilocaine I.P. as active ingredients in strength of 2.50% w/w for each.

The excipients used are Carbopol Ultrez, Cresmer RH 40, Butylated Hydroxy Toluene, Methyl Paraben, and Sodium Hydroxide.

TOPLAP GEL is available in pack of 10 gm and 30 gm.

10. Details of manufacturer

Pure & Cure Healthcare Pvt. Ltd.

(A subsidiary of Akums Drugs & Pharmaceuticals Ltd.)

Plot No. 26A, 27-30, Sector-8A, I.I.E.,

SIDCUL, Ranipur, Haridwar-249 403, Uttarakhand

11. Details of permission or licence number with date

Mfg. Licence. No.: 361 issued on: 08-2023

12. Date of revision

Aug-2023

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/TOPLAP GEL 10 gm and 30 gm/Aug-23/02/PI