TOPOCAIN-LP CREAM

Consumer Medication Information Leaflet (RiMUP)

Lidocaine 2.5% w/w and Prilocaine 2.5% w/w

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What Topocain-LP cream is used for

Topocain-LP cream contains two active substances called lidocaine and prilocaine. These belong to a group of medicines called local anaesthetics.

Adults, Adolescents and Children

It can be used to numb the skin before:

- Having a needle put in (for example, if you are having an injection or a blood test).
- Minor skin operations.

Adults and Adolescents

It can also be used:

- To numb the genitals before having an injection and medical procedures such as removal of warts.

Adults

It can also be used to numb the skin before:

- Cleansing or removal of damaged skin of leg ulcers.

How Topocain-LP cream works

Topocain-LP cream works by numbing the surface of the skin for a short time. It is put on the skin before certain medical procedures. This helps to stop pain on the skin; however, you may still have the feelings of pressure and touch.

Before you use Topocain-LP cream

- When you must not use it

Do not use Topocain-LP cream if:

- You are allergic to lidocaine or prilocaine, other similar local anaesthetics or any of the other ingredients of this product.

- Before you start to use it

Tell your doctor if:

- You or your child have a rare inherited illness that affects the blood called 'glucose-6- phosphate dehydrogenase deficiency'.
- You and your child have a problem with blood pigment levels called 'methaemoglobinaemia'.
- Do not use Topocain-LP cream on areas with skin rash, cuts, grazes or other open wounds, with the exception of a leg ulcer. If any of these problems are present, check with your doctor, pharmacist or nurse before using the product.
- You and your child have an itchy skin condition called 'atopic dermatitis', a shorter application time maybe sufficient. Application times of longer than 30 minutes may result in an increased incidence of local skin reaction.
- You take particular products for heart rhythm disorders (class III antiarrhythmics, such as amiodarone). In that case the doctor will monitor your heart function.

- Taking other medicines

Tell your doctor or pharmacist if you are using / taking, have recently used / taken or might use / take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Topocain-LP cream can affect the way some medicines work and some medicines can have an effect on Topocain-LP cream.

In particular, tell your doctor or pharmacist if you or your child have recently used or been given any of the following medicines:

- Medicines used to treat infections, called 'sulphonamides'.
- Other local anaesthetics.
- Medicines to treat an uneven heartbeat, such as amiodarone.
- Cimetidine or beta-blockers, which may cause an increase in the blood levels of lidocaine. This interaction is of no clinical relevance in short-term treatment with Topocain-LP cream in recommended doses.

How to use Topocain-LP cream

- How much to use

Use on the skin before small procedures (such as having a needle put in or minor skin operations):

- The cream is put on to the skin in a thick layer. Follow the instructions on the leaflet or those from your healthcare professional. In certain cases, your healthcare professional has to apply the cream.
- The cream is then covered by a dressing (plastic wrap). This is taken off just before the procedure starts. If you are applying the cream yourself, make sure you have been given dressings by your doctor, pharmacist, or nurse.
- The usual dose for adults and adolescents over 12 years is 2g (grams).
- For adults and adolescents over 12 years, put the cream on at least 60 minutes before the procedure (unless the cream is being used on the genitals). However, do not put it on more than 5 hours before.

Children

Use on the skin before small procedures (such as having a needle put in or minor skin operations) – Application time: approximately 1 hour.

Newborn infants and infants 0-3 months:

Up to 1g of cream on a skin area not larger than $10cm^2$ in size. Application time: 1 hour, not more. Only one single dose should be given in any 24- hour period.

Infants aged 3-12 months:

Up to 2g of cream on a total skin area not larger than $20cm^2$ in size.
Application time: approximately 1 hour.

Children aged 1-6 years:

Up to 10g of cream on a total skin area not larger than $100cm^2$ in size.
Application time: approximately 1 hour, maximum 5 hours.

Children aged 6-12 years:

Up to 20g of cream on a total skin area not larger than $200cm^2$ in size.

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Application time: approximately 1 hour, maximum 5 hours.
Topocain-LP cream can be used on children with a skin condition called "atopic dermatitis" but the application time is 30 minutes, no longer.

Use on the skin before hospital procedures (such as split-skin grafting) that require deeper skin anaesthesia:
- Topocain-LP cream can be used in this way on adults and adolescents over 12 years, but only under the supervision of a doctor or nurse.
- The usual dose is 1.5g to 2g of cream for each area of skin that is $10cm^2$ in size.
- The cream is put on under a dressing for 2 to 5 hours.

Use on the skin prior to removal of wart-like spots called "mollusca":
- Topocain-LP cream can be used on children and adolescents with a skin condition called "atopic dermatitis".
- The usual dose depends on the child's age and is used for 30 to 60 minutes (30 minutes if the patient has atopic dermatitis). Your doctor, nurse, or pharmacist will tell you how much cream to use.

Use on the genital skin before injections of local anaesthetics:
- Topocain-LP cream can be used in this way only by healthcare professionals on adults and adolescents over 12 years.
- The usual dose is 1 g of cream (1g to 2g for female genital skin) for each area of skin that is $10cm^2$ in size.
- The cream is put on under a dressing. This is done for 15 minutes on male genital skin and for 60 minutes on female genital skin.

Use on the genitals before minor skin surgery (such as removal of warts):
- Topocain-LP cream can be used in this way only by healthcare professionals on adults and adolescents over 12 years.
- The usual dose is 5g to 10g of cream for 10 minutes. A dressing is not used. The medical procedure should then start straight away.

Use on leg ulcers before cleaning or removal of damaged skin:
- Topocain-LP cream can be used in this way in adults, but only under the supervision of a doctor or nurse.
- The usual dose is 1 g to 2 g of cream for each area of skin that is $10cm^2$ up to a total of 10g.
- The cream is put on under an airtight dressing such as plastic wrap. This is done for 30 to 60 minutes before the ulcers to be cleaned. Remove the cream with cotton gauze and start cleansing without delay.
- Topocain-LP cream can be used before cleansing of leg ulcers for up to 15 times over a period of 1-2 months.
- Topocain-LP cream is indicated for single use when used on leg ulcers. The tube with any remaining contents should be discarded after each occasion that a patient has been treated.

- When to use it
Your doctor will decide when it is appropriate for you to use Topocain-LP cream according to the type of condition you have

- How long to use it
Continue taking use Topocain-LP cream for as long as doctor recommends.

- If you forget to use it
Consult your doctor or pharmacist on what you should do if you forget to use it.

- If you use too much (overdose)
If you use more Topocain-LP cream that is described in the leaflet or more than your doctor, pharmacist or nurse has told you to, talk to them straight away, even if you do not feel any symptoms.

Symtomps of using too much Topocain-LP cream are listed below. These symptoms are unlikely to happen if Topocain-LP cream is used as recommended.
- Feeling light-headed or dizzy.
- Tingling of the skin around the mouth and numbness of the tongue.
- Abnormal taste.
- Blurred vision.
- Ringing in the ears.
- There is also a risk of 'acute methaemoglobinaemia' (a problem with blood pigment levels). This is more likely when certain medicines have been taken at the same time. If this happens, the skin becomes bluish-grey due to lack of oxygen.

In serious case of overdose, symptoms may include fits, low blood pressure, slowed breathing, stopped breathing and altered heartbeat. These effects may be life-threatening.

While you are using it
- Things you must do
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Topocain-LP cream.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do
- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give Topocain-LP cream to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of
Avoid getting Topocain-LP cream in the eyes, as it may cause irritation. If you accidentally get Topocain-LP cream in your eye, you should immediately rinse it well with lukewarm water or salt (sodium chloride) solution. Be careful to avoid getting anything in your eye until feeling returns.

Side effects

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Like all medicines, Topocain-LP cream can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following side effects have been reported:

- Allergic reactions, which in rare cases may develop into anaphylactic shock (skin rash, swelling, fever, respiratory difficulties and fainting) during treatment of skin, genital mucosa or leg ulcers.
- Methaemoglobinaemia (blood disorder), which in rare cases may develop during treatment of the skin, and may cause signs and symptoms of hypoxaemia (abnormally low level of oxygen in the blood). Methaemoglobinaemia is more frequently observed, often in connection with overdose, in newborn infants and infants aged 0 to 12 months.

A mild reaction (paleness or redness of the skin, slight puffiness, initial burning or itching) may occur on the area on which Topocain-LP cream is used. These are normal reactions to the cream and the anaesthetics and will disappear in a short while without any measures being needed.

If you experience any troublesome or unusual effects while you are using Topocain-LP cream, stop using it and check with your doctor or pharmacist as soon as possible.

Common (may affect up to 1 in 10 people)

- Transient local skin reactions (paleness, redness, swelling) in the treated area during treatment of skin, genital mucosa or leg ulcers.
- An initially mild sensation of burning, itching or warmth at the treated area during treatment of genital mucosa or leg ulcers.

Uncommon (may affect up to 1 in 100 people)

- An initially mild sensation of burning, itching or warmth at the treatment area during treatment of the skin.
- Numbness (tingling) in the treated area during treatment of genital mucosa.
- Irritation of the treated skin during treatment of leg ulcers

Rare (may affect up to 1 in 1,000 people)

- Small dot-shaped bleeding on the treated area (particularly on children with eczema after longer application times) during treatment of the skin.
- Irritation of the eyes if Topocain-LP cream accidentally comes into contact with them during treatment of the skin.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers-> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Topocain-LP cream

- Storage

Store below 30°C. Do not freeze.

Keep out of the reach of children.

- Disposal

Do not use Topocain-LP cream after the expiry date which is stated on the carton. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

White homogenous cream

- Ingredients

- Active ingredients:
Lidocaine, Prilocaine

- Inactive ingredients:

- Croduret 60-SO (SG) (Ethoxylated hydrogenated castor oil)
- Carbopol 934P NF Polymer (Carbomer 934 P)
- Sodium Hydroxide
- Purified water

MAL number:

MAL*********

Manufacturer

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Product Registration Holder

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Date of revision

18/09/2026

Serial number

NPRA (R2) 25/230