numit[™] 5% cream

Active ingredient(s): lidocaine and prilocaine

Consumer Medicine Information (CMI)

This leaflet provides important information about using numit 5% cream. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using numit 5% cream.

Where to find information in this leaflet:

- 1. Why am I using numit 5% cream?
- 2. What should I know before I use numit 5% cream?
- 3. What if I am taking other medicines?
- 4. How do I use numit 5% cream?
- 5. What should I know while using numit 5% cream?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using numit 5% cream?

numit 5% cream contains the active ingredients lidocaine and prilocaine, both are local anaesthetics.

These local anaesthetics are combined with special agents which allow the products to pass through the skin. Once through the skin the numbing effect they produce allows minor surgical procedures to be

performed with a complete or significant reduction in pain.

These procedures can include insertion of IV catheters, mechanical cleansing or debridement of leg ulcers, blood sampling, vaccination, superficial surgical procedures, including split skin grafting; minor superficial cosmetic procedures. Topical anaesthesia of genital skin prior to superficial surgical procedures or infiltration analgesia.

numit 5% cream is not addictive.

2. What should I know before I use numit 5% cream?

Warnings

Do not use numit 5% cream if:

- you are allergic to lidocaine or prilocaine, or any of the ingredients listed at the end of this leaflet.
 Always check the ingredients to make sure you can use this medicine.
- you have any open wounds except leg ulcers.

Check with your doctor or pharmacist if you:

 have any other medical conditions, e.g. dermatitis, methaemoglobinaemia, glucose-6-phosphate dehydrogenase deficiency and mollusca contasgiosa. It may not be safe for you or your child to use numit 5% cream if you have any of these conditions.

- take any medicines for any other condition
- intend to use it to treat other complaints
- have allergies to local anaesthetic, eg those used at the dentist
- have allergies to adhesives or sticking plasters
 If you or your child have an allergic reaction, you may get a skin rash, hay fever or an asthma attack.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant. The ingredients in numit 5% cream have been used for many years and no ill effects have been shown if they are used while you are pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed. Only very small amounts of numit 5% cream get into the blood so there is a risk your baby can take in numit 5% cream from breast milk if you are breast feeding, it is unlikely to cause any problems.

numit 5% cream should not be used in premature babies.

We do not have enough knowledge yet to be sure if it is safe in premature babies.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with numit 5% cream and affect how it works.

- a sulphonamide antibiotic eg sulfatrimoxazole
- medicines used to treat irregular heartbeat such as amiodarone
- other local anaesthetic

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect numit 5% cream.

4. How do I use numit 5% cream?

How much to use

- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage as this can cause harmful side effects, particularly in infants under 3 months of age.

When to use numit 5% cream

On intact skin:

The most important thing to do is be sure that you apply numit 5% cream at least one hour before you are due to have the procedure except for skin grafting where a two hour application time is required or for procedures on male genital skin where only fifteen minutes is required.

Leg ulcers:

If you are using numit 5% cream on leg ulcers you only need to apply the cream 30 minutes before your ulcer is going to be cleaned.

numit 5% cream can be left on for several hours and still work.

If you use too much numit 5% cream

If you think that you have used too much numit 5% cream, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Do not exceed the maximum recommended dose or length of administration. Children, particularly those aged below 3 months of age, are at an increased risk of serious adverse effects in overdose.

For most procedures, it is difficult to use too much numit 5% cream. Be careful not to use too much in procedures where larger amounts may be required, such as cosmetic hair removal (see Package Insert for maximum amounts). Using too much numit 5% cream may cause unwanted side effects. Some of these can be serious such as methaemoglobinaemia (a condition where the blood cannot take enough oxygen to your blood) or cardiovascular effects (effects on your heart and lungs). If you use too much numit 5% cream, you may notice the following:

- nervousness
- dizziness
- difficulty breathing
- numbness of the mouth
- your skin turning blue (a symptom of methaemoglobinaemia)
- blurred vision
- shaky hands
- a rash where numit 5% cream has not been applied.

5. What should I know while using numit 5% cream?

Things you should do

Be sure to follow the instructions in the pack insert on how to apply numit 5% cream carefully.

Make sure the dressing covering cream is firmly fixed, especially on young children.

If you or your child are using numit 5% cream on leg ulcers, only use the tube once. Throw out any cream left in the tube after use.

Remind any doctor, dentist or pharmacist you visit that you are using numit 5% cream.

Things you should not do

- Do not use on broken skin, unless a doctor has told you to.
- Do not apply to large areas of the body, except on the advice of a healthcare practitioner.
- If you do not follow the application duration instruction, your or your child's appointment may have to be delayed, or the procedure may hurt more than it would otherwise.
- Do not apply near eyes. It may cause eye irritation. If numit 5% cream does get into your eyes, immediately rinse them with large amounts of water and contact your doctor or pharmacist for advice.

- Do not use numit 5% cream on leg ulcers for longer than 2 months without checking with your doctor or pharmacist.
- Do not exceed the recommended dose. Exceeding the recommended dose or length of application may be harmful.

Looking after your medicine

- Keep your cream in the pack until it is time to use it.
- If you squeeze too much numit 5% cream out of the tube it should be discarded, it should not be kept.
- Do not let it freeze.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 30°C. Keep away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Mild side effects

Less serious side effects	What to do
Skin: Any local reaction such as itching, swelling, paleness, redness or a burning sensation.	Remove numit 5% cream and discontinue use. Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Rare side effects

Serious side effects	What to do
Skin:A rash at a spot where numit 5% cream is not being used.	Remove numit 5% cream and discontinue use. Call your doctor straight away, or go straight to the Emergency Department at your

Serious side effects	What to do
 Areas of skin becoming blue (a symptom of - methaemoglobinaemia) Eye sight: blurred vision. 	nearest hospital if you notice any of these serious side effects.
Respiratory: difficulty breathing	
Head: dizziness	
Hands: shaky	

Please refer to 'If you use too much numit 5% cream' for specific side effects as a result of overdose.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What numit 5% cream contains

Active ingredient (s)	Lidocaine,
(main ingredient (s))	Prilocaine
Other ingredients	Carbomer 934P,
(inactive ingredients)	Ethoxylated hydrogenated castor oil,
	Purified water,
	Sodium hydroxide

Do not take this medicine if you are allergic to any of these ingredients.

What numit 5% cream looks like

numit 5% cream is a soft glossy cream in either a 10g or 30g tube (Aust R 265292). 5g tube is not currently marketed.

Who distributes numit 5% cream

Ego Pharmaceuticals Pty. Ltd.

13-31 Malcolm Road, Braeside 3195

Australia.

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