NUMIT 5% cream

Lidocaine (lignocaine) and prilocaine

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about NUMIT.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child using NUMIT against the benefits they expect it will have for you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What is NUMIT used for?

NUMIT is a mixture of two local anaesthetics, lidocaine (lignocaine) and prilocaine.

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 taking blood samples, vaccination, skin grafting, cleaning leg ulcers, inserting an intravenous catheter, minor superficial cosmetic procedures and procedures on genital skin.

Numit is available as a cream which is applied then covered with a dressing.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

Your doctor or pharmacist may prescribe this medicine for another use. Ask your doctor or pharmacist if you want more information.

NUMIT is not addictive.

Before you use NUMIT

When you must not use this product

Do not apply NUMIT cream to any open wounds except leg ulcers.

Do not use NUMIT if you are pregnant or breastfeeding unless your doctor says it is safe.

The ingredients in NUMIT have been used for many years and no ill effects have been shown if they are used while you are pregnant.

Only very small amounts of NUMIT get into the blood so even though so even though your baby can take in NUMIT from breast milk if you are breast feeding.

NUMIT should not be used in premature babies.

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

Do not use after the use by (expiry) date printed on the pack or the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not use it to treat any other complaints unless your doctor says it is safe.

Do not give this medicine to anyone else.

Before you start to use it

You must tell your doctor or pharmacist about any of these.

- 1. allergies you or your child have to any
- ingredients listed at the end of this leaflet
- local anaesthetic, for example those used at the dentist

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.

- 2. any of these medical conditions
- dermatitis
- methaemoglobinaemia
- glucose-6-phosphate dehydrogenase deficiency
- mollusca contasgiosa

It may not be safe for you or your child to use NUMIT if you have any of these conditions.

Taking other medicines

Tell your doctor of pharmacist if you are using any other medicines including

- a sulphonamide antibiotic eg sulfatrimoxazole
- medicines used to treat irregular heartbeat such as amiodarone
- medicines that you buy at your pharmacy, supermarket or health food shop
- other local anaesthetics.

These medicines may affect the way NUMIT works or may cause adverse effects.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

How to use **NUMIT**

Directions

NUMIT is available as a cream.

Instructions on how to use NUMIT are included in the carton. Please read them carefully. The instructions also give maximum doses for adults and children. Do not exceed the maximum doses.

On intact skin

The most important thing to do is be sure that you apply NUMIT 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 on leg ulcers you only need to apply the cream 30 minutes before your ulcer is going to be cleaned.

NUMIT can be left on for several hours and still work.

If you forget to use it

Apply NUMIT as soon as you realise it if it is less than an hour until you are supposed to have the procedure. Tell your

doctor exactly when you put NUMIT on and they will decide when the procedure can take place.

If you have trouble remembering when to use your medicines, ask your pharmacist for some hints.

If you take too much (overdose)

Telephone your doctor or Poisons Information Centre (13 11 26), or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have used too much NUMIT even if there are no signs of discomfort or poisoning.

For most procedures, it is difficult to use too much NUMIT. 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 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, 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 has not been applied.

While you are using NUMIT

Things you must not do

Remember to apply NUMIT on intact skin at least one hour before your procedure is due. For leg ulcers remember to apply NUMIT 30 minutes before your ulcer is due to be cleaned. Apply NUMIT two hours before split skin grafting and at least fifteen minutes before a procedure on male genital skin.

If you do not, your or your child's appointment may have to be delayed, or the procedure may hurt more than it would otherwise.

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

Things to be careful of

Do not use NUMIT cream on leg ulcers for longer than 2 months without checking with your doctor or pharmacist.

Be sure to follow the instructions in the pack on how to apply NUMIT cream carefully.

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

Be careful not to let NUMIT get into the eyes.

It may cause eye irritation. If NUMIT does get into your eyes, immediately rinse them with large amounts of water and contact your doctor or pharmacist for advice.

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child do not feel well while using NUMIT.

NUMIT helps most people to undergo minor procedures without feeling pain, but it may have unwanted side effects in a few people. All medicines have side effects.

Sometimes they are serious, most of the time they are not.

You may need medical treatment if you or your child get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

 any local reaction such as itching, swelling, paleness, redness or a burning sensation.

These are all mild side effects of NUMIT.

If any of the following happen, remove NUMIT and tell your doctor immediately or go to casualty at your nearest hospital.

- a rash at a spot where NUMIT is not being used.
- difficulty breathing
- dizziness
- shaky hands
- blurred vision
- areas of skin becoming blue

These are very serious side effects. If you or your child have them, you or your child may have had a serious reaction to NUMIT and urgent medical attention or hospitalisation may be required.

All of these side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you or your child feel unwell.

Some people may get other side effects.

After using NUMIT

Storage

Keep your cream in the pack until it is time to use it.

If you squeeze NUMIT out of the tube it will not keep well.

Keep NUMIT in a cool dry place where the temperature stays below 30°C. Do not let it freeze.

Do not store NUMIT or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any NUMIT you have left over if your doctor tells you to stop using it, or you find that it has expired.

Shelf life

Do not use NUMIT after the expiry date printed on the pack. If you use it after the expiry date has passed, it may not work as well.

Product description

NUMIT cream contains:

- lidocaine (lignocaine)
- prilocaine

- carbomer 934P
- castor oil ethoxylated hydrogenated
- water purified

For further information

This is not all the information that is available for NUMIT.

If you have any questions or are not sure about anything, ask your doctor or pharmacist.

Manufacturer

Ego Pharmaceuticals Pty. Ltd.

21-31 Malcolm Road, Braeside 3195

Australia.

Australian Registration number:

AUST R 265292.

Date of approval of leaflet: 29/09/2015.