

Package leaflet: Information for the patient

Nulbia 5% cream

Lidocaine + Prilocaine

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

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nulbia is and what it is used for
2. What you need to know before you use Nulbia
3. How to use Nulbia
- 4 Possible side effects
5. How to store Nulbia
6. Contents of the pack and other information

1. What Nulbia is and what it is used for

Nulbia contains two active substances called lidocaine and prilocaine. These belong to a group of medicines called local anaesthetics.

Nulbia 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.

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.
 - Medical procedures such as removal of warts.

A doctor or nurse should apply Nulbia on the genitals.

Adults

It can also be used to numb the skin before:

- Cleansing or removal of damaged skin of leg ulcers

For other purposes than application to intact skin, the product should be used only upon recommendation of a doctor, nurse or pharmacist.

2. What you need to know before you use Nulbia

Do not use Nulbia:

- If you are allergic to lidocaine or prilocaine, other similar local anaesthetics or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Nulbia:

- if you or your child have a rare inherited illness that affects the blood called “glucose-6-phosphate dehydrogenase deficiency”.
- if you or your child have a problem with blood pigment levels called “methaemoglobinaemia”.
- do not use Nulbia 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 cream.
- if you or your child have an itchy skin condition called “atopic dermatitis”, a shorter application time may be sufficient. Application times of longer than 30 minutes may result in an increased incident of local skin reaction (see also section 4 “Possible side effects”).
- if you take particular products for heart rhythm disorders (class III antiarrhythmics, such as amiodarone). In that case the doctor will monitor your heart function.

Due to the potentially enhanced absorption of the newly shaven skin, it is important to follow the recommended dosage, skin area and application time.

Avoid getting Nulbia in the eyes, as it may cause irritation. If you accidentally get Nulbia 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.

Nulbia should not be applied to an impaired eardrum.

When you use Nulbia before being vaccinated with live vaccines (e.g. tuberculosis vaccine), you should return to your doctor or nurse after the time period requested to follow-up the vaccination result.

Children and adolescents

In infants/newborn infants younger than 3 months a transient, clinically not relevant increase in blood pigment levels “methaemoglobinaemia” is commonly observed up to 12 hours after Nulbia is put on.

The effectiveness of Nulbia when drawing blood from the heel of newborn infants or to provide adequate analgesia for circumcision could not be confirmed in clinical studies.

Nulbia should not be applied to the genital skin (e.g. penis) and genital mucosa (e.g. in the vagina) of children (below 12 years of age) owing to insufficient data on absorption of active substances.

Nulbia should not be used in children younger than 12 months of age who are being treated at the same time with other medicines that affect blood pigment levels “methaemoglobinaemia” (e.g. sulphonamides, see also Section 2 Other medicines and Nulbia).

Nulbia should not be used in preterm newborn infants.

Other medicines and Nulbia

Tell your doctor or pharmacist if you are using/taking, or 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 Nulbia can affect the way some medicines work and some medicines can have an effect on Nulbia.

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” and nitrofurantoin.
- Medicines used to treat epilepsy, called phenytoin and phenobarbital.
- 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 Nulbia in recommended doses.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Occasional use of Nulbia during pregnancy is unlikely to have any adverse effects on the foetus.

The active substances in Nulbia (lidocaine and prilocaine) are passed into breast milk. However, the amount is so small that there is generally no risk to the child.

Animal studies have shown no impairment of male or female fertility.

Driving and using machines

Nulbia has no or negligible influence on the ability to drive and use machines when used at the recommended doses.

Nulbia contains castor oil polyoxyl hydrogenated.

Castor oil polyoxyl hydrogenated may cause skin reactions.

3. How to use Nulbia

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

Using Nulbia

- Where to put the cream, how much to use and how long to leave it on will depend on what it is used for. Half a 5 g tube corresponds to about 2 g Nulbia. One gram of Nulbia pressed out of a tube is approximately 3.5 cm.
- Nulbia should be used on the genitals only by a doctor or nurse.
- When Nulbia is used on leg ulcers, a doctor or nurse should supervise its use.

Do not use Nulbia on the following areas:

- Cuts, grazes or wounds, excluding leg ulcers.
- Where there is a skin rash or eczema.
- In or near the eyes.
- Inside the nose, ear or mouth.
- In the back passage (anus).
- On the genitals of children.

Persons frequently applying or removing cream should ensure that contact is avoided in order to prevent the development of hypersensitivity.

The protective membrane of the tube is perforated by applying the cap.

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 health care 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 that you have been given dressings by your doctor, pharmacist or nurse.
- The usual dose for adults and adolescents over 12 years is 2 g (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: approx. **1 hour.**

Newborn infants and infants 0-2 months: Up to 1 g of cream on a skin area not larger than 10 cm² (10 square centimetres) in size. Application time: **1 hour, not more. Only one single dose should be given in any 24 hour period.**

Infants aged 3-11 months: Up to 2 g of cream on a total skin area not larger than 20 cm² (20 square centimetres) in size. Application time: approx. **1 hour**, maximum 4 hours.

Children aged 1-5 years: Up to 10 g of cream on a total skin area not larger than 100 cm² (100 square centimetres) in size. Application time: approx. **1 hour**, maximum 5 hours.

Children aged 6-11 years: Up to 20 g of cream on a total skin area not larger than 200 cm² (200 square centimetres) in size. Application time: approx. **1 hour**, maximum 5 hours.

A maximum of 2 doses at least 12 hours apart may be given to children over 3 months of age in any 24 hour period.

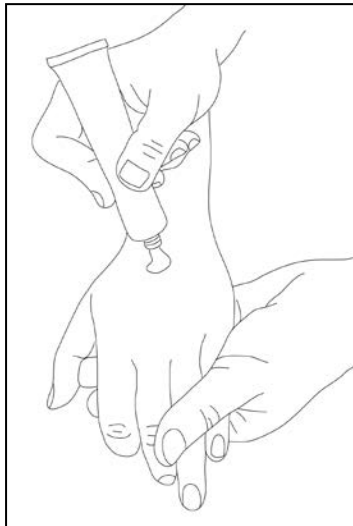
Nulbia can be used on children with a skin condition called “atopic dermatitis” but the application time is then 30 minutes, no longer.

When you apply the cream, it is very important to exactly follow the instructions below:

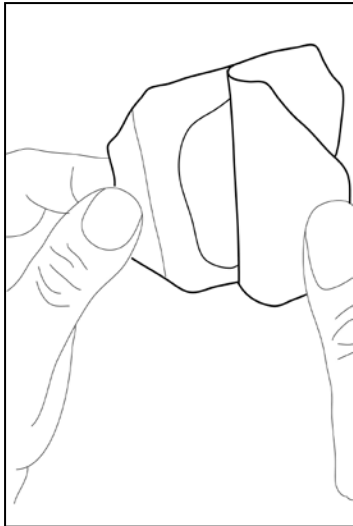
1. Squeeze the cream into a mound where it is needed on your skin (for example where the needle is going to be put in).

Half a 5 g tube corresponds to about 2 g Nulbia. One gram of cream pressed out of a tube is approximately 3.5 cm.

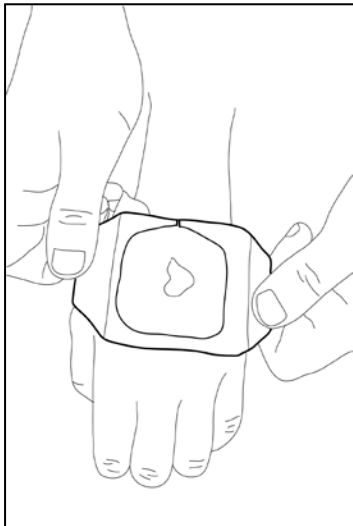
Do not rub the cream in.



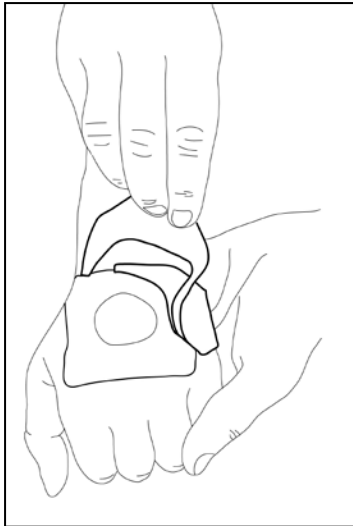
2. Remove the covers of the dressing.



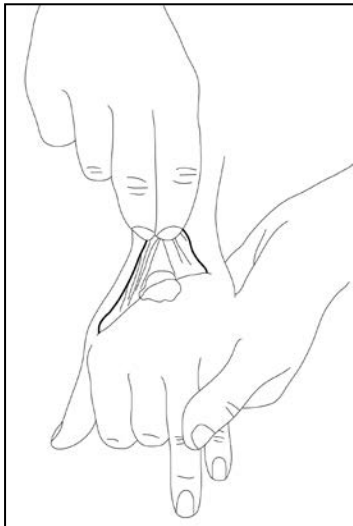
3. Then place the dressing carefully over the mound of the cream. Do not spread the cream under the dressing.



4. Remove the paper backing. Smooth down the edges of the dressing carefully. The application time depends on your age and indication. Application times are shown in section 3 of this leaflet.



5. Your doctor or nurse will take the dressing off and remove the cream just before they do the medical procedure (for example just before the needle is put in).



Use on larger areas of newly shaven skin before outpatient procedures (such as hair removal techniques):

Follow the instructions from your health care professional.

The usual dose is 1 g of cream for each area of skin that is 10 cm² (10 square centimetres) in size, applied for 1 to 5 hours under a dressing. Nulbia should not be used on an area of newly shaven skin larger than 600 cm² (600 square centimetres, e.g. 30 cm by 20 cm) in size. The maximum dose is 60 g.

Use on the skin before hospital procedures (such as split-skin grafting) that require deeper skin anaesthesia:

- Nulbia 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 1.5 g to 2 g of cream for each of area of skin that is 10 cm² (10 square centimetres) 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”

- Nulbia 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 genital skin before injections of local anaesthetics

- Nulbia 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 2 g for female genital skin) for each area of skin that is 10 cm² (10 square centimetres) 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)

Nulbia can be used in this way only by healthcare professionals on adults and adolescents over 12 years.

The usual dose is 5 g to 10 g 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

- Nulbia can be used in this way in adults, but only under the supervision of a doctor or nurse.
- The usual dose is 1g to 2 g of cream for each area of skin that is 10 cm² up to a total of 10 g.
- The cream is put on under an airtight dressing such as plastic wrap. This is done for 30 to 60 minutes before the ulcer is to be cleansed. Remove the cream with cotton gauze and start cleansing without delay.
- Nulbia can be used before cleansing of leg ulcers for up to 15 times over a period of 1-2 months.

- The Nulbia tube is intended 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.

If you use more Nulbia than you should

If you use more Nulbia than what is described in this leaflet or more than your doctor, pharmacist or nurse have told you to, talk to one of them straight away, even if you do not feel any symptoms.

Symptoms of using too much Nulbia are listed below. These symptoms are unlikely to happen if Nulbia 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 a lack of oxygen.

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

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Contact your doctor or pharmacist if any of the following side effects bother you or do not seem to go away. Tell your doctor about anything else that makes you feel unwell while you are using Nulbia.

A mild reaction (paleness or redness of the skin, slight puffiness, initial burning or itching) may occur on the area on which Nulbia 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 Nulbia, 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 treated area during treatment of the skin.
- Numbness (tingling) in the treated area during treatment of the genital mucosa
- Irritation of the treated skin during treatment of leg ulcers.

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

- 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) during treatment of the skin.
- 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 Nulbia accidentally comes into contact with them during treatment of the skin.

Additional side effects in children

Methaemoglobinaemia, a blood disorder, which is more frequently observed, often in connection with overdose in newborn infants and infants aged 0 to 12 months.

Reporting of side effects

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nulbia

Store below 30°C. Do not refrigerate or freeze.

After first opening use within 6 months.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package and tube after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Nulbia contains

- The active substances are lidocaine and prilocaine. Each gram of cream contains 25 mg of lidocaine and 25 mg of prilocaine.
- The other ingredients are Castor oil polyoxyl hydrogenated, carbomer 974P, sodium hydroxide and water purified.

What Nulbia looks like and contents of the pack

Nulbia is a white soft cream. It is presented in collapsible aluminium tubes of 5g and 30g, internally covered with an epoxyphenolic lacquer.

Pack sizes:

1 x 30g tube

1 x 5g tube

1 x 5g tube with 2 dressings

1 x 5g tube with 3 dressings

5 x 5g tubes

5 x 5g tubes with 12 dressings

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in September 2017