Package leaflet: Information for the user

DENELA 5% CREAM
(For 30 g surgical packs)

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 has 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 DENELA CREAM is and what it is used for

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

Denela 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.

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 supervise the use of Denela Cream 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 DENELA CREAM

Do not use Denela Cream:

- 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 Denela Cream:

- 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 Denela 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 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 incidence 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 on the newly shaven skin, it is important to follow the recommended dosage, skin area and application time.

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

Denela Cream should not be applied to an impaired eardrum.

When you use Denela Cream before being vaccinated with live vaccines (e.g. tuberculosis vaccines), 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 Denela Cream is put on.

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

Denela Cream 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.

Denela Cream 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 Denela Cream).

Denela Cream should not be used in preterm newborn infants.

Other medicines and Denela Cream

Tell your doctor, pharmacist or nurse 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 Denela Cream can affect the way some medicines work and some medicines can have an effect on Denela Cream.

In particular, tell your doctor, pharmacist or nurse 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 Denela Cream in recommended doses.

Pregnancy, breastfeeding 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 Denela Cream during pregnancy is unlikely to have any adverse effects on the foetus.

The active substances in Denela Cream (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
Denela Cream has no or negligible influence on the ability to drive and use machines when used at the recommended doses.

Denela Cream contains macrogolglycerol hydroxystearate.
May cause skin reactions.

3. How to use DENELA CREAM

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 Denela Cream
- 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 Denela. One gram of Denela pressed out of a tube is approximately 3.5 cm.
- Denela Cream should be used on the genitals only by a doctor or nurse.
- When Cream is used on leg ulcers, a doctor or nurse should supervise its use.

Do not use Denela Cream 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 cm^2 (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 cm^2 (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 cm^2 (100 square centimetres) in size. Application time: approx **1 hour**, maximum 5 hours.

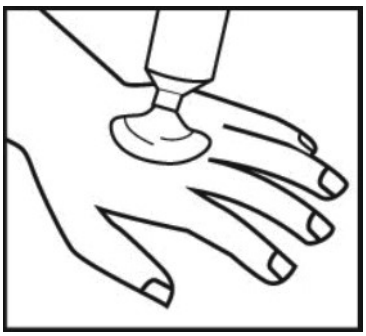
Children aged 6-11 years: Up to 20 g of cream on a total skin area not larger than 200 cm^2 (200 square centimetres) in size. Application time: approx **1 hour**, maximum 5 hours.

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.

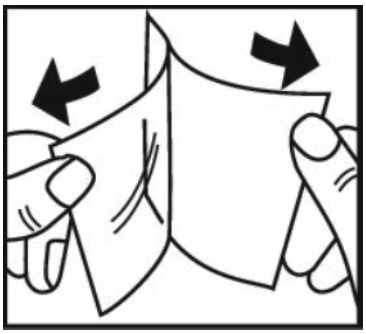
Denela Cream can be used on children with a skin condition called “atopic dermatitis” but the application time is then 30 minutes, no longer.

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

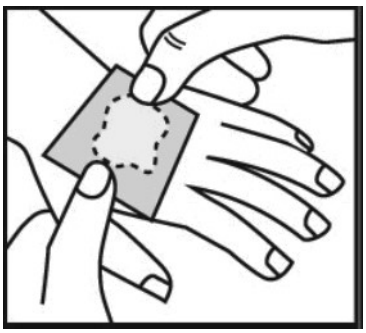
1. Squeeze the cream into a mound where it is needed on your skin (for example where the needle is going to be put in). Half a 5 g tube corresponds to about 2 g Denela Cream. One gram of Denela Cream pressed out of a tube is approximately 3.5 cm. Do not rub the cream in.



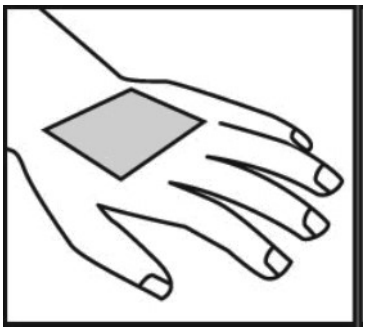
2. Peel the paper layer from the dressing.



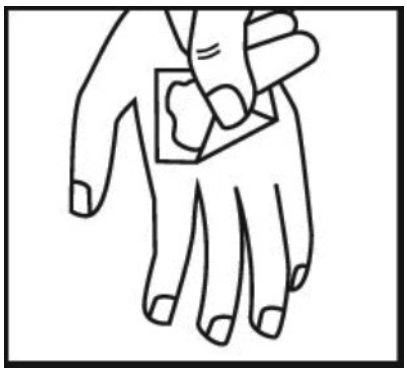
3. Remove the cover of the adhesive side of the dressing. Then place the dressing carefully over the mound of cream. Do not spread the cream under the dressing.



4. Remove the plastic backing. Smooth down the **edges** of the dressing carefully. Then leave it in place for at least 60 minutes if the skin has not been damaged. The cream should not be left in place for more than 60 minutes in children under 3 months or for more than 30 minutes in children with an itchy skin condition called 'atopic dermatitis'. If the cream is used on the genitals or on ulcers, shorter applications times may be used as described below.



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 cm^2 (10 square centimetres) in size, applied for 1 to 5 hours under a dressing. Denela Cream should not be used on an area of newly shaven skin larger than 600 cm^2 (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:

- Denela 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 1.5 g to 2 g of cream for each area of skin that is 10 cm^2 (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"

- Denela 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 genital skin before injections of local anaesthetics

- Denela 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 (1 g to 2 g for female genital skin) for each area of skin that is 10 cm^2 (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)

- Denela Cream 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

- Denela 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 10 cm^2 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.
- Denela Cream can be used before cleansing of leg ulcers for up to 15 times over a period of 1-2 months.
- The Denela Cream 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 Denela Cream than you should:

- If you use more Denela Cream 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 Denela Cream are listed below. These symptoms are unlikely to happen if Denela 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 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 Denela.

A mild reaction (paleness or redness of the skin, slight puffiness, initial burning or itching) may occur on the area on which Denela 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 Denela, 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 intially 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 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 Denela Cream 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (Website: www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DENELA CREAM

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 carton and the tube after (MM/YYYY). The expiry date refers to the last day of that month.

Store below 25 °C and do not freeze.

This medicine should be disposed of 3 months after first opening.

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 protect the environment.

6. Contents of the pack and other information

What Denela Cream 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 macrogolglycerol hydroxystearate (hydrogenated polyoxyl castor oil), carbomer (974P), sodium hydroxide and purified water.

What Denela Cream looks like and contents of the pack:

Denela 5% Cream is a white soft cream.

Pack sizes:
30 g tube with a wooden spatula

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Teva UK Limited,
Ridings Point,
Whistler Drive,
Castleford,
WF10 5HX,
United Kingdom

Manufacturer:
Tiofarma B.V.
Benjamin Franklinstraat 5-10
3261 LW Oud-Beijerland
The Netherlands

This leaflet was last revised in January 2023

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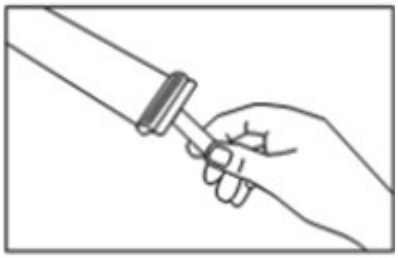
The following information is intended for medical or healthcare professionals only:
(Please detach prior to giving the leaflet to the patient)

DENELA 5% CREAM
(For 30 g surgical packs)
Lidocaine & Prilocaine

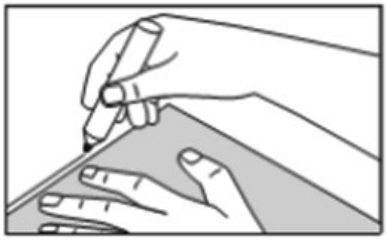
Application instructions for surgical use only (split skin grafting)

Apply approximately 1.5-2 g/10 cm^2 Denela 5% Cream, at least 2 hours and not more than 5 hours before split skin graft procedure.

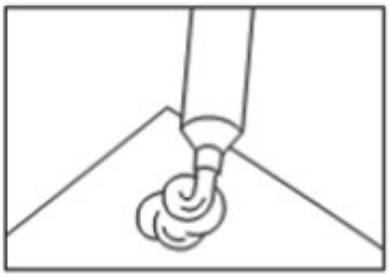
1. Shave the skin of the selected donor site area. Clean the area of skin with alcohol.



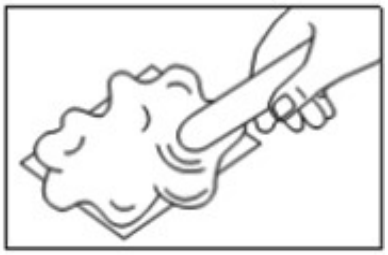
2. Select the exact area of the donor site by using the graduated ruled edge of this leaflet, e.g. 10 cm x 10 cm or 10 cm x 20 cm – and mark this area using an indelible thick marker pen to delineate the margins of the site.



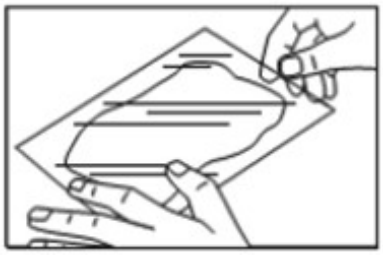
3. Squeeze out between ½ -1 (30g) tube of Denela 5% Cream per 100 cm^2 on the area of the donor site to be anaesthetised.



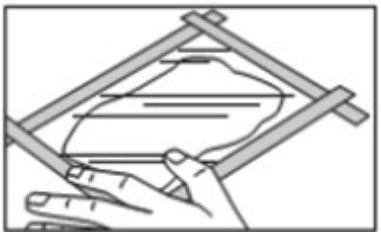
4. Spread the Denela 5% Cream using the enclosed spatula to form an even thick layer. It is important to cover completely the entire donor area including over the marked margins of the site.



5. Take a strip of transparent occlusive plastic film wrapping cut to the appropriate size (slightly larger than the area of the donor site). Carefully apply the wrapping to cover completely the layer of Denela 5% Cream.



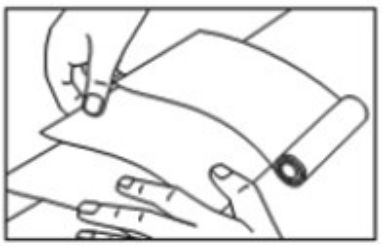
6. Smooth down and tape the edges of the occlusive film wrapping to the skin using a surgical synthetic adhesive tape.



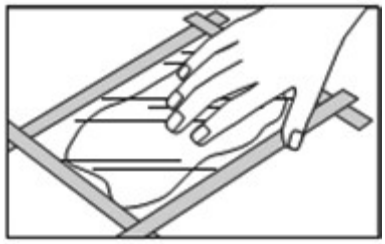
7. Wrap the entire site using an elastic crepe bandage to protect the site and avoid leakage of the Denela 5% Cream – but avoid undue compression and do not wrap too tight.

   Leave the Denela 5% Cream and occlusive wrapping in place for at least 2 hours.

   As a reminder, the time can be written on the wrapping or bandage.



8. After 1 hour and hourly thereafter – remove only the crepe bandage (not the adhesive tape or film wrapping) and massage the Denela 5% Cream through the film wrapping to ensure a thick, even layer of Denela is maintained over the entire donor site. Replace the bandage.



9. After a minimum of 2 hours – just prior to surgery – remove the bandage and occlusive wrapping. Wipe off the Denela 5% Cream. Analgesic efficacy may decline if application time is > 5 hours.

   The anaesthetised donor site may appear either pale or red. These reactions are normal and are associated with the skin anaesthesia. Disinfect and prepare the anaesthetised donor site prior to cutting the split skin graft.