

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

- **Read this leaflet.**
- **If you have any further questions, ask your doctor, pharmacist, or nurse.**
- **This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.**
- **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 this leaflet:

1. What Prila Cream is and what it is used for
2. What you need to know before you use Prila Cream
3. How to use Prila Cream
4. Possible side effect
5. How to store Prila Cream
6. Further information

1. What Prila Cream is and what it is used for.

PRILA Cream contains two Active substance called lidocaine and prilocaine. These belong to a group of medicines called local anaesthetics. PRILA 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).
- Medical operations.

Adults and Adolescents

It can also be used:

- To numb the genitals before:
 - o Having an injection.
 - o Medical procedures such as removal of warts.

A doctor or nurse should apply PRILA Cream on the genitals.

Adults

It can also be used to numb the skin before:

- Cleansing or removal of damaged skin of leg ulcers.
- Before you have an 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 Prila Cream.

Do not use Prila 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 Prila Cream:

- If you or your child have a rare inherited illness that affects the blood called "methemoglobinemia" or "methemoglobinemia".
- If you or your child have a problem with blood pigment levels called "methemoglobinemia".
- Do not use PRILA 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 PRILA Cream in the eyes, as it may cause irritation. If you accidentally get PRILA 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.

PRILA Cream should not be applied to an impaired ear drum. Avoid getting PRILA Cream in the eyes, as it may cause irritation. If you accidentally get PRILA 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.

Children and adolescents

In infants/newborn infants younger than 3 months a transient, clinically not relevant increase in blood pigment levels "methemoglobinemia" is commonly observed up to 12 hours after PRILA Cream is put on. The effectiveness of PRILA Cream when drawing blood from the heel of newborn infants or to provide adequate analgesia for circumcision could not be confirmed in clinical studies.

PRILA 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. PRILA 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 "methemoglobinemia" (e.g. sulfonamides, see also Section 2 Other medicines and PRILA Cream).

Other medicines and PRILA Cream

Tell your doctor, pharmacist or nurse if you are using/ taking, have recently used or take or might use:

- Any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because PRILA Cream can affect the way some medicines work and some medicines can have an effect on PRILA 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 'sulfonamides' and nitrofurantoin.
- Medicines used to treat epilepsy, called phenytoin and phenobarbital.
- Other local anaesthetics.
- Medicines to treat an uneven heartbeat, such as amiodarone.
- Bloodline 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 PRILA Cream in recommended doses.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, 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 PRILA Cream during pregnancy is unlikely to have any adverse effects on the foetus.

The active substances in PRILA 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

PRILA Cream has no or negligible influence on the ability to drive and use machines when used as the recommended doses.

PRILA Cream contains macroglycol ether oleyl oxystearate

Macroglycol ether oleyl oxystearate may cause skin reactions.

3. How to use Prila Cream.

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

This product is available in different pack sizes. You will have been provided with a suitable pack size for your intended use.

Using PRILA 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 PRILA Cream. One gram of PRILA Cream pressed out of a tube of 30g is approximately 3.5 cm.
- PRILA Cream should be used on the genitals only by a doctor or nurse.
- When PRILA Cream is used on leg ulcers, a doctor or nurse should supervise its use.
- Do not use PRILA 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 a small procedure (such as having a needle put in or minor skin operation).

- 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 most 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 a small procedure (such as having a needle put in or minor skin operation) 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.

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.

PRILA 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 PRILA Cream. One gram of PRILA Cream pressed out of a tube of 30g is approximately 3.5 cm. Do not rub the cream in.
2. Peel the paper layer from the 'centre cut-out' of the non-adhesive side of the dressing (leaving a frame of paper).
3. Remove the cover of the adhesive side of the dressing.
4. Place the dressing carefully over the mound of cream. Do not spread the cream under the dressing.
5. Remove the paper 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.
6. 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 procedure (such as hair removal techniques):

Follow the instructions from your healthcare 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. PRILA 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 5 g.

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

- PRILA 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"

PRILA 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

- PRILA 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 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 a minor skin surgery (such as a removal of wart)

- PRILA 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 a cleaning or a removal of damaged skin

PRILA 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 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 cleaned. Remove the cream with cotton gauze and start cleansing without delay.
- PRILA can be used before cleansing of leg ulcers for up to 15 times over a period of 1-2 months.
- The PRILA 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 PRILA Cream than you should.

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

Symptoms of using too much PRILA Cream are listed below. These symptoms are unlikely to happen if PRILA 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 methaemoglobinemia (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 everyone 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 PRILA Cream.

If you experience any of the following effects while you are using PRILA Cream, stop using it and check with your doctor or pharmacist as soon as possible:

- 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.
- Methaemoglobinemia (blood disorder), which in rare cases may develop during treatment of genital mucosa, leg ulcers, and may cause signs and symptoms of hypoxaemia (abnormally low level of oxygen in the blood). Methaemoglobinemia is more frequently observed, often in connection with overdose, in newborn infants and infants aged 0 to 12 months.

A mild reaction (paleless or redness of the skin, slight puffiness, initial burning or itching) may occur on the area on which PRILA 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 PRILA, 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 (paleless, 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 genital mucosa.

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 PRILA Cream accidentally comes into contact with them during treatment of the skin.

Very rare (may affect up to 1 in 10,000 people)

- Anaphylactic 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.

5. How to store Prila Cream.

- Keep out of the sight and reach of children.
- Do not use Prila Cream after the expiry date which is stated on the carton and label after "EXP". The expiry date refers to the last day of that month.
- Shelf life after first opening is 30 days.
- Store below 30°C and do not freeze.
- 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.

6. Further information

What Prila 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 Cremophore RH 40, Carbomer 934M, Sodium Hydroxide, and Purified water.

What Prila Cream looks like and the contents of the pack

Collapsible aluminium tube with white HDPE screw cap. Pack containing tubes x 5 g or 1 tube x 30 g.

Manufacturer & Marketing Authorisation Holder:

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To report any side effect(s):

Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC)

- SFDA call center: 19999
- E-mail: npc.drug@safda.gov.sa
- Website: <https://aids.safda.gov.sa>

Other GCC States:

Please contact the relevant competent authority.

THIS IS A MEDICATION

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medication.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep a record of all medicines used at each of your visits.

Council of Arab Health Ministers, Union of Arab Pharmacists