

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986**

This medicine can be marketed without a doctor's prescription

LIDOPRI-AVENIR 5% cream

Active ingredients and their concentration:

Composition:

Lidocaine 2.5%

Prilocaine 2.5%

For the list of excipients and allergens, see 'Important information about some of the ingredients of the medicine' and section 6 'Additional information'.

Read this entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

Use the medicine in the correct manner. Consult a pharmacist if you need additional information.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is the medicine used for?

LIDOPRI-AVENIR 5% is used for dermal local anesthesia, for pain relief before procedures involving the insertion of a needle (e.g., infusion, blood tests) and superficial skin operations.

LIDOPRI-AVENIR 5% cream works by temporarily numbing the skin so that it helps relieve the pain. However, you may still feel touch and pressure in the area.

Therapeutic group:

Local anesthetic of the amide group.

2. Before using the medicine

Do not use the medicine if:

If you are sensitive (allergic) to one of the active ingredients or to any of other ingredients of the medicine, or to another similar local anesthetic (see section 6).

Special warnings regarding the use of the medicine

Before treatment with LIDOPRI-AVENIR 5%, tell your doctor if:

- You or your child have a rare inherited illness that affects the blood, called "glucose-6-phosphate dehydrogenase deficiency" (G6PD enzyme, sensitivity to fava beans).
- You or your child have a problem with blood pigment levels called "methemoglobinemia".
- Do not use LIDOPRI-AVENIR 5% on areas with skin rash, cuts, grazes, scratches or other open wounds, with the exception of a leg ulcer. If any of these problems is present, check with the doctor or pharmacist before using the medicine.
- You or your child have itchy skin condition called "atopic dermatitis". A shorter application time on the skin may be sufficient. Application times of the cream on

the skin for more than 30 minutes can cause an increase in the incidence of local skin reactions (see also section 4 "Side effects").

- You take particular medicines 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 newly shaven skin, it is important to follow the recommended dosage, skin areas and application time of the cream on the skin.

Avoid getting LIDOPRI-AVENIR 5% cream in the eyes, as it may cause irritation. If LIDOPRI-AVENIR 5% cream accidentally gets in the eyes, immediately rinse the eyes well with lukewarm water or a saline (sodium chloride) solution. Be careful to avoid getting anything in the eye until feeling returns.

Do not apply LIDOPRI-AVENIR 5% to an impaired eardrum.

When you use LIDOPRI-AVENIR 5% before being vaccinated with live vaccines (e.g., tuberculosis vaccine), you should return to the doctor or nurse after the time period requested to follow-up the vaccination result.

In children - do not use on genital mucosa (see also section 3).

In the following cases refer to the doctor before starting the treatment:

- In infants under one year of age that are concomitantly treated with methemoglobinemia inducing medicines such as sulfonamides ("sulfa drugs").
- In premature infants until they have reached the chronological age of 37 weeks.

Drug interactions

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription medicines, nutrition supplements and herbal remedies. This is because LIDOPRI-AVENIR 5% cream can affect the way certain medicines work, and some medicines can have an effect on LIDOPRI-AVENIR 5%.

In particular, tell the doctor or pharmacist if you are taking:

- Medicines used to treat infections, called "sulfonamides" and nitrofurantoin.
- Medicines used for the treatment of epilepsy, called phenytoin and phenobarbital.
- Other local anesthetics.
- Medicines used for the treatment of uneven heartbeat such as amiodarone.
- Cimetidine or beta-blockers, which may cause an increase in the blood levels of lidocaine. This drug interaction is of no clinical relevance in short-term treatment with LIDOPRI-AVENIR 5% at the recommended dosages.

Pregnancy, breastfeeding and fertility

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before using this medicine.
- Occasional use of LIDOPRI-AVENIR 5% during pregnancy is unlikely to cause any adverse effects on the fetus.
- The active ingredients in LIDOPRI-AVENIR 5% (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

LIDOPRI-AVENIR 5% has no or negligible influence on the ability to drive and use machines when used at the recommended doses.

Important information about some of the ingredients of the medicine

LIDOPRI-AVENIR 5% contains macroglycerol hydroxystearate which may cause skin reactions.

3. How to use the medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to use this medicine.

See further down: "Measuring the correct amount of cream"

Do not use LIDOPRI-AVENIR 5% cream on mucous membranes or damaged skin without consulting the doctor. In such cases you need to reduce the application time of the cream.

Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:

Dosage in adults (over 12 years of age):

For minor surgical procedures (such as needle insertion for an IV infusion or when taking blood tests, or curettage of viral skin infections (mollusca contagiosum)): Approximately 1.5-2 grams for every 10 cm² of skin surface. Apply a thick layer of the cream, cover it with an occlusive dressing, such as plastic wrap, and wait 1-5 hours.

For surgical procedures requiring deeper local anesthesia:

Approximately 1.5-2 grams for every 10 cm² of skin surface. Apply a thick layer of the cream, cover it with an occlusive dressing, such as plastic wrap, and wait 2-5 hours.

Maximum dose: Up to 60 grams per day (2 tubes of 30 grams) may be applied. Do not leave the cream on a treated area for longer than 5 hours.

LIDOPRI-AVENIR 5% cream should not be applied on an area of recently shaven skin larger than 600 cm² (20x30 cm).

For removal of leg ulcers - apply 1-2 grams for every 10 cm² of skin. Apply a thick layer of cream on the area of the ulcer, but not more than 10 grams for each treatment. Cover with an occlusive dressing and dispose of any remaining cream left in the tube. Application time: at least 30 minutes. In cases of tissues with particularly difficult permeability, the application time can be extended to a maximum of 60 minutes.

Removing the ulcer should start within 10 minutes after cream removal. LIDOPRI-AVENIR 5% can be used for up to 15 treatments over a period of 1-2 months without decrease in the effect or increase in the number of local reactions.

On genitalia (men only) - before injection of local anesthetics - apply approximately 1 gram for each area of skin that is 10 cm². Cover with an occlusive dressing for 15 minutes.

On genitalia (women) - before injection of local anesthetics - apply approximately 1-2 grams for each area of skin that is 10 cm². Cover with an occlusive dressing for 60 minutes.

On genital mucosa (adults only) - prior to minor skin surgeries such as a surgery for removing condylomas: apply 5-10 grams, depending on the size of the treated area. Cover the whole area, including the mucosal folds. Occlusion is not necessary. Application time: 5-10 minutes. The surgery should be started immediately after removal of the cream.

Dosage in children:

For use on the skin before medical procedures such as needle insertion or minor skin surgeries. Apply about an hour before procedure.

Do not exceed the recommended dose (see dosage table).

When used in infants up to 3 months of age, methemoglobin tests should be performed before and after use.

In children, do not use LIDOPRI-AVENIR 5% on the mucous membranes of the genitalia.

Dosage table in infants and children

Age and body weight	Maximal amount of LIDOPRI-AVENIR 5% cream	Maximal application area	Maximal duration on the skin
Up to 3 months / up to 5 kg	1 gram	10 cm ²	1 hour
3-12 months / 5-10 kg	2 grams	20 cm ²	4 hours
1-6 years / 10-20 kg	10 grams	100 cm ²	4 hours
7-12 years / over 20 kg	20 grams	200 cm ²	4 hours

In children with atopic dermatitis, remove the cream 15-30 minutes after application.

Applying additional doses:

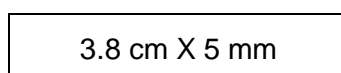
In infants up to 3 months of age - do not apply another dose for 24 hours.

In infants and children over 3 months of age – wait at least 12 hours until reapplying LIDOPRI-AVENIR 5%. Do not apply more than 2 doses within 24 hours.

Measuring the right amount of cream (for use in children and adults):

To measure 1 gram of LIDOPRI-AVENIR 5%, the cream should be gently squeezed out of the tube as a narrow strip that is 3.8 cm long and 5 mm wide. The strip of cream should be contained within the lines of the diagram shown below:

Strip ≈ 1 gram



Do not exceed the recommended dose.

See detailed instructions for use at the end of this leaflet.

Do not swallow! This medicine is intended for external use only.
Avoid contact of the medicine with the eyes, mucous membranes and the ears. In case of contact, wash thoroughly with water. Protect the eye until sensation is restored to the eye.

If you have applied more than recommended, you may experience: blue-grey colored skin, drowsiness or dizziness, blurred vision or ringing in the ears, changes in taste, confusion, hot/cold or paresthesia sensation, tingling of the skin around the mouth and numbness of the tongue.

In severe cases of overdose the following may occur: spasms, decrease in blood pressure, slowed breathing, stopped breathing and altered heart rate – evacuate the patient to the emergency room immediately!

If you have applied more LIDOPRI-AVENIR 5% cream than recommended or if a child has accidentally swallowed some medicine, refer immediately to a doctor or hospital emergency room and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. Side effects:

Like all medicines, the use of LIDOPRI-AVENIR 5% cream may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Refer to your doctor or pharmacist if any of the following side effects bothers you or does not seem to be passing. Tell your doctor about anything else that is causing you to feel unwell while you are using LIDOPRI-AVENIR 5%.

If you experience any of the following effects while you are using LIDOPRI-AVENIR 5% 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.
- Methemoglobinemia (blood disorder), which in rare cases may develop during treatment of the skin, and may cause signs and symptoms of hypoxemia (abnormally low levels of oxygen in the blood). Methemoglobinemia is more frequently observed, often in connection with overdose, in newborn infants and infants aged 0 to 12 months.

A mild reaction (paleness or redness of the skin, slight puffiness, an initial burning sensation or irritation) may occur on the area on which LIDOPRI-AVENIR 5% cream is applied. These are normal reactions to the cream and the anesthetics, and they will disappear within a short time without any additional measures being needed.

If you experience worrisome or unusual effects when you use LIDOPRI-AVENIR 5% cream, stop using the cream and check with your doctor or the pharmacist as soon as possible.

Common side effects (appear in 1-10 users out of 100):

- 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, irritation or warmth in the treated area during treatment of genital mucosa or leg ulcers.

Uncommon side effects (appear in 1-10 users out of 1,000):

- An initially mild sensation of burning, irritation or warmth in 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 side effects (appear in 1-10 users out of 10,000):

- Small dot-shaped bleeding on the treated area (particularly in children with eczema after longer application times of the cream) during treatment of the skin.
- Irritation of the eyes if LIDOPRI-AVENIR 5% comes into contact with them during treatment of the skin.

If a side effect appears, if one of the side effects worsens, or when you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Side effects and drug interactions in children and infants:

Parents must inform the attending doctor about any side effects, as well as any additional medicine given to the child. See above detailed side effects and particular drug interactions.

Reporting of side effects:

Side effects may be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.it) which refers you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.it>

5. How to store the medicine?

- Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants, in order to avoid poisoning. **Do not induce vomiting unless explicitly instructed to do so by a doctor.**
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Store the medicine below 25°C.
- LIDOPRI-AVENIR 5% cream can be used up to 6 months after first opening the tube, when stored below 25°C, but not later than the expiry date.
- Do not dispose of the medicine via wastewater or household waste. Consult your pharmacist on how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients this medicine also contains:

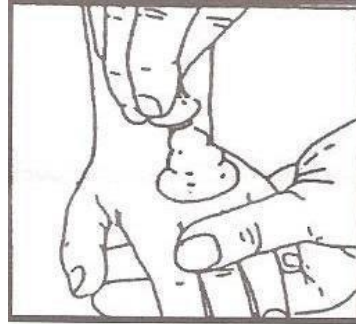
Macrogolglycerol hydroxystearate, Carbomers (Carbopol 980 NF), Sodium hydroxide, Purified water.

What the medicine looks like and contents of the pack:

LIDOPRI-AVENIR 5% cream is a homogenous white cream packed in an aluminum tube of 5 grams or 30 grams.

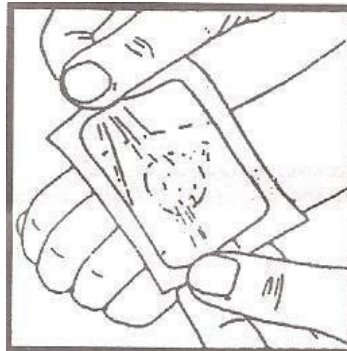
Directions for use:

1. Squeeze the LIDOPRI-AVENIR 5% tube to extract a sufficient amount (see dosage instructions) and apply a thick layer of the cream on the skin. Do not rub the area.



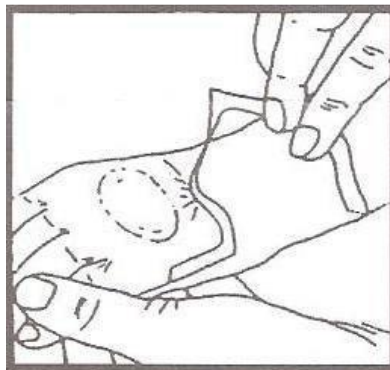
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2. Cover the skin to which LIDOPRI-AVENIR 5% was applied with an occlusive dressing, such as plastic wrap. Secure it firmly, make sure that all of the cream is covered.



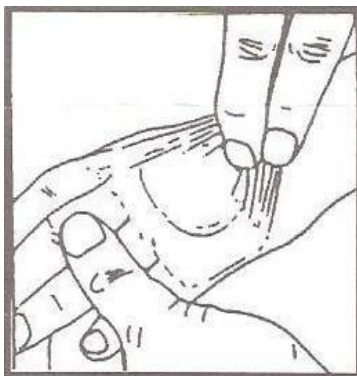
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3. Wait the necessary period of time (usually at least an hour) before performing the required treatment.



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4. Remove the dressing, wipe off the LIDOPRI-AVENIR 5% cream and prepare for the required treatment. The area treated with LIDOPRI-AVENIR 5% will remain anesthetized for at least 30 minutes and up to several hours.



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Name and address of manufacturer: Aguetant Laboratories, 1 Alexander Fleming Street - 69007 Lyon Cedex, France

Registration holder and address: BioAvenir Ltd., 1 David Hamelech St., Herzelia Pituach.

Revised in December 2021 according to MOH guidelines

Registration number of the medicine in the Ministry of Health's National Drug Registry: 162-80-35307-00