



## PATIENT INFORMATION LEAFLET

# LAMINOX CREAM 1%

For Topical use

- **Drug substance:** Each gram of the cream contains 10 mg terbinafine hydrochloride.
- **Excipients:** Sodium hydroxide, benzyl alcohol, sorbitan monostearate (Span 60), cetyl palmitate, cetyl alcohol, stearyl alcohol, polysorbate 60, isopropyl myristate, deionized water.

**Read this LEAFLET carefully before you start taking this medicine, as it contains important information:**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your physician or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others.
- Inform your physician that you are using this medicine during your visits to the physician or to the hospital.
- Follow strictly these instructions. Do not use this drug in any doses higher or lower than recommended.

### In this leaflet:

1. What is LAMINOX and what it is used for?
2. Important notice to know prior taking LAMINOX
3. How to Take LAMINOX
4. What are the possible side effects?
5. How to store LAMINOX

### 1. What is LAMINOX and what it is used for?

LAMINOX cream is a drug effective against fungus diseases. It is effective by killing the fungi causing skin problems or by stopping their growth.

LAMINOX cream is used for the treatment of athlete's foot (Tinea pedis), cures most jock itch (Tinea cruris), ringworm (tinea corporis), heat rash (Candidiasis) and yeast infections such as Pityriasis versicolor.

LAMINOX is marketed in aluminum tube containing 15 gram cream which is closed by a plastic cap.

### 2. Important notice to know prior taking LAMINOX

DO NOT USE LAMINOX in the following cases:  
If:

- Hypersensitive (allergic) to Terbinafine or any of the ingredients of LAMINOX.

### Use LAMINOX carefully in the cases below

- LAMINOX cream is for external use only. Do not use to treat the infections in the mouth or do not swallow. After the cream application, wash your hands. Do not apply the cream near your eyes and prevent any contact between the cream and your eyes. If the cream contacts your eyes, remove the cream, wash your eyes with water properly. If any effect is observed, consult your physician.
- LAMINOX cream contains cetyl alcohol and stearyl alcohol having possibility to cause local skin irritation.
- Because some fungal infections are contagious, be sure that you use your own towel and clothes and do not share these with others. To prevent re-infection, wash your towel and clothes frequently.

Please consult your physician, if these statements were applicable to you at any time even in the past.

### Taking LAMINOX with food or drinks

LAMINOX can be taken with or without food.

### Pregnancy

Before drug administration, contact your physician or pharmacist.

If you think you are pregnant or if you are planning to get pregnant, first consult your physician. LAMINOX cream should not be used during pregnancy, unless it is absolutely necessary.

If you realize that you are pregnant during the treatment, contact your physician or pharmacist immediately.

### Breast-feeding

Before drug administration, contact your physician or pharmacist.

Mothers using LAMINOX cream should not breast feed.

Prevent any contact between your baby and the sites where you applied LAMINOX cream, including breasts.

### Effects on the use of device and machine

It is not possible for topical administration of LAMINOX to affect the device/machine use ability.

### Important information about the excipients found in the formulation of LAMINOX

LAMINOX cream contains cetyl alcohol and stearyl alcohol; they have the possibility to cause local skin reactions (e.g. contact dermatitis).

### Taking LAMINOX cream with other drugs

Do not apply other medical products at the same places with LAMINOX.

*Please inform your physician or pharmacist if you are currently using or recently used any prescription or non-prescription drugs.*

### 3. How to take LAMINOX

#### Recommendations for appropriate usage and dosage/administration frequency:

Apply LAMINOX cream to infected sites as following:

- Athlete's foot (Tinea pedis): For one week once a day.
- Jock itch (Tinea cruris), Ringworm (tinea corporis): For one week once a day.
- Heat rash (Skin candidiasis): For one week once or twice a day.
- Pityriasis versicolor: For two weeks once or twice a day.

Although infection ameliorates in a few days, continue to use LAMINOX cream for the recommended treatment duration. If LAMINOX cream is not used regularly or treatment is stopped early, re-infection can occur.

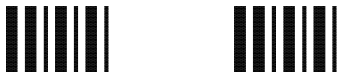
Your skin infection should get better in several days after starting LAMINOX. However, after the infection has gone, total recovery of the skin will take longer time. The effects of LAMINOX will continue after the treatment and recovery will continue.

*If there is no recovery in 2 weeks after starting the treatment, contact your physician or pharmacist.*

#### Route and method of administration:

Apply the cream as following:

- Clean the affected skin and the surroundings and wash your hands.
- The tube will be sealed for the first use. Open the seal by using the sharp end of the closure.
- Take some amounts of the cream on your finger.
- Apply the cream to the infected skin and its surrounding in thin layer.



- Apply the cream by slowly rubbing.
- Wash your hands. If not, you may transfer the infection to the healthy skin.

If the infected skin is between fingers or hips, on the breasts or on armpit or on pubic region, after applying the cream, you may close the skin with gauze bandage. This is recommended especially while sleeping. New gauge bandage should be used after each administration.

For the treatment to be successful, infected skin should be clean by washing regularly. Dry the skin by slowly touching it. Do not scratch this region even if it is itching because it may slow down the treatment process or spread the infection.

#### **Different age groups:**

##### **Administration for children:**

The safety of the use of LAMINOX cream for children has not been proved. It is not suggested to use LAMINOX cream for children under 12 years of age.

##### **Administration for old patients:**

LAMINOX cream can be used for the patients above the age of 65 years.

#### **Special administration cases**

##### **Kidney/liver deficiency:**

There is no data for dose adjustment for the patients having kidney or liver deficiency.

Please follow these advices, unless your physician suggests others.

Your physician will let you know the period of the treatment. Do not stop the treatment early, because stopping LAMINOX cream treatment may result in worsening the conditions of your disease.

If you have the impression that the effect of LAMINOX is either very potent or very weak, please talk to your physician or pharmacist.

#### **If you apply LAMINOX cream more than you should:**

If you use more than the suggested amount of cream, it is enough to wipe it. It does not cause any harm.

If you or somebody else, especially a child, swallows LAMINOX cream, immediately call your physician or pharmacist. They will tell you what should be done in this case.

If you have used higher doses than the suggested dose, contact your physician or pharmacist.

#### **If you forget a dose of LAMINOX:**

If you forget a dose, apply as soon as you remember and continue with your instructed mode of administration. If you remember the forgotten dose at the time of the next dose, apply only the normal amount of the next dose and continue with your instructed mode of administration.

Use the cream as mentioned in this user's guide. If you discontinue or miss the applications of LAMINOX cream, infection may re-occur.

*Do not apply a double dose to make up for a forgotten dose.*

#### **Possible effects after discontinuation of the treatment with LAMINOX**

Stopping LAMINOX treatment may worsen your disease. Unless it is recommended by your physician, do not stop the treatment.

#### **4. What are the possible side effects?**

Like all the other drugs, there can be adverse effects in patients having sensitivity to the compounds found in the formulation.

**Discontinue LAMINOX and IMMEDIATELY contact your physician or seek medical assistance at the nearest emergency station in the case of the following:**

- Panicula and pain, skin rash or urticarial (signs of allergic reactions)

Those are all serious adverse effects.

If you have any of those, stop the application, it means you are allergic to LAMINOX.

It may be necessary to seek immediate medical assistance or hospitalization.

Those serious adverse effects are very rare.

**If you realize any of the following situations, contact your physician or your pharmacist.**

- Redness at the application site.
- Itching or stinging may occur.

Those are light adverse effects of LAMINOX.

*If you notice any side effects not listed in this leaflet, please tell your physician or pharmacist.*

#### **5. How to store LAMINOX**

Keep out of the sight and reach of children and in its pack. Store at room temperature below 25°C. Keep the tube tightly closed.

Use in concordance with the expiry date.

Do not use after the expiry date mentioned on the package.

If you notice damage in the product and/or in its package, do not use LAMINOX.

#### **Marketing Authorisation Holder and Manufacturer**

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