

PATIENT INFORMATION LEAFLET

LAMINOX 250 mg TABLETS

Tablets for oral administration

• Active ingredients:

Contains 250 mg terbinafine hydrochloride.

• Excipients:

Aerosil 200, magnesium stearate, sodium starch glycolate, HPMC-E5, Avisel PH 102, 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 at 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 is presented in blister packs containing 14 tablets.

LAMINOX tablet is used to treat a number of fungal infections of the skin and nails.

LAMINOX tablet is used also in the treatment of skin yeast infections and skin tinea (fungal infection) infection including infections of the scalp and hair, pubis and other parts of the body, foot (athlete's foot) and nail (onychomycosis).

Terbinafine is an anti-fungal agent that belongs to the allylamine anti-fungal category and is used in the treatment of fungal infections of the skin, hair and nails. It reaches high levels to kill or to stop reproduction of fungi at the infection site when administered via the oral route.

2. Important notice to know prior taking LAMINOX

DO NOT USE LAMINOX in the following cases:

If:

- You are allergic (hypersensitive) to terbinafine or any of the excipients listed in this patient information leaflet, or contained in the formulation of LAMINOX,
- You experience past or present health problems associated with hepatic disorders,
- You are experiencing any renal problems.

TAKE SPECIAL CARE WITH THE USE OF LAMINOX in the following cases

If:

- You are using other medication (see: concomitant use with other drugs),
- You experience signs of unexplained persistent nausea, vomiting, abdominal pain, loss of appetite and much tiredness; jaundice of skin or eyeballs, dark urine or pale stools (symptoms of liver disorder).
- Skin rash, reddish skin, peeling; blisters in the lips, eyes or mouth (symptoms of serious skin reactions).
- Tiredness, unexpected bleeding, bruising or frequently recurring infection (symptoms of hematological disorders).

Please ask your physician for advice if you experienced any of these signs even during any period in the past.

Taking LAMINOX with food

While the use of LAMINOX with food moderately affects the drug entrance to the blood circulation, such influence does not require dose adjustments.

Pregnancy

Ask your physician or pharmacist for advice before taking any medicine.

Tell your physician if you are pregnant or planning to become pregnant. The use of LAMINOX in pregnant women is not recommended unless strictly necessary. Your physician will inform you on the potential risks of the use of LAMINOX during pregnancy.

Immediately ask your physician or pharmacist if you become aware of your pregnancy during the treatment.

Breast-feeding

Ask your physician or pharmacist for advice before taking any medicine.

Since terbinafine passes into breast milk and may have undesirable effects on the infant, breast-feeding is not recommended while using LAMINOX. It may be harmful for the infant.

Driving and using machines

You should not use vehicles or machines if you experience dizziness while using LAMINOX tablets.

Important information on some excipients contained in LAMINOX

No negative effects associated with the excipients contained in the formulation of LAMINOX are expected unless you are oversensitive to these excipients.

Using other medicines

Inform your physician if you are using:

- Some antibiotics (e.g. rifampicine),
- Caffeine,
- Some anti-depressants such as desipramine,
- Some medicines used in the management of cardiologic disorders (e.g. propafenone, amiodarone),
- Some medicines used in the management of high blood pressure (hypertension) (such as metoprolol),
- Some medicines used in the management of gastric ulcers (e.g. cimetidine).
- Medicines used in the treatment of fungal infections (e.g. fluconazole, ketoconazole),
- Some drugs used in the treatment of cough (e.g. dextrometorphane),
- Cyclosporine, an immunosuppressive agent intended for the control of your immune system in order to prevent the rejection of transplanted organs, and
- Warfarin, a blood thinning anticoagulant.

Please tell your physician or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. How to take LAMINOX?

Instructions on the appropriate use and dose / administration frequency:

Follow strictly your physician's instructions. Do not exceed the recommended dose. If you have the impression that the effect of LAMINOX is either very potent or very weak, please talk to your physician or pharmacist.

Adults:

The usual dose is 250 mg tablet once a day.

Children:

No data is available for children younger than 2 years of age (usually less than 12 kg). Children weighing between 20 and 40 kg, 125 mg once a day (1/2 tablet LAMINOX). Children weighing over 40 kg, 250 mg once a day (1 tablet LAMINOX).

How long LAMINOX should be used?

This will depend on the type and severity of infection and the size of the affected site of the body. Your physician will inform you on the exact duration for the use of the tablets.

The ordinary duration of the treatment:

LAMINOX tablet is usually taken for 2 to 6 weeks for fungal infection (tinea) of the foot (athlete's foot).

LAMINOX tablet is usually taken for 2 to 4 weeks in fungal (tinea) and yeast infections of the pubis and other areas of the body.

It is important to take your tablet(s) daily and continue treatment for the period instructed by your physician. This will ensure complete cure of the infection and reduce the possibility of recurrence after treatment.

Hair and scalp infections:

Usual period of treatment of fungal infections (tinea) of the hair and scalp is 4 weeks.

Nail infections:

Fungal infections of the nails usually take longer to recover than the fungal infections of the skin. LAMINOX tablets should be taken for 6 to 12 weeks in many cases of nail infection.

Infections of the fingernails:

Treatment period of 6 weeks is sufficient for most cases.

Infections of the toenails:

Treatment period of 12 weeks is sufficient for most cases.

Patients with weak nail outgrowth may need prolonged treatment periods. Your physician will inform you about this matter.

Route and method of administration:

LAMINOX tablet is administered via the oral route only. You may take LAMINOX tablet with or without food. Ingest the tablet with a glass of water.

There are some precautions to be considered in the prevention, the recovery and the recurrence of the infection. You may, for example, keep the infected areas cool and dry and change your clothing in contact with the infection site (or sites) on daily basis.

Various age groups:

Use in children:

Safety of the use in children has not been established. The use of LAMINOX tablet in children younger than 2 years is not recommended.

Use in the elderly:

LAMINOX tablet can be used in patients older than 65 years of age. Patients over 65 years are given the same doses as adults.


Special precautions for use:

Renal / Hepatic impairment:

The use of LAMINOX tablet is not recommended if you have past or existing health problems associated with liver or any renal impairment.

Follow these instructions unless recommended otherwise by your physician.

Your physician will inform you on the duration of your LAMINOX treatment. Do not discontinue the treatment prematurely as discontinuing LAMINOX may result in the worsening of your condition.



Please consult your physician or pharmacist if you are not sure.

If you have taken more LAMINOX than required:

Please consult your physician or pharmacist if you took LAMINOX in an amount higher than required.

Immediately consult your physician if you have accidentally used more tablets than the amount recommended by your physician. You may require medical treatment. Symptoms of LAMINOX overdose include headache, nausea, gastric pain and dizziness.

If you forget to take LAMINOX

Immediately take the tablet(s) as soon as you remember if more than 4 hours are left until next administration of LAMINOX tablet. Otherwise, wait and take your next dose in the ordinary course.

Do not take twice the dose to make up the forgotten dose.

Possible effects after discontinuation of the treatment with LAMINOX

Discontinuing the treatment with LAMINOX may lead to the worsening of your condition. Do not discontinue the treatment unless instructed by your physician.

4. What are the possible side effects?

As is the case with all medicines, LAMINOX may cause side effects in patients who are sensitive to the ingredients.

The use of LAMINOX may result in the following side effects:

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

- Although LAMINOX may rarely cause liver problems, such problems can be serious at rare occasions.
- Very rare side effects include decrease in some blood cell types, autoimmune (a case related to the body immune system) diseases (lupus) or serious skin reactions including severe allergic reactions.
- Blood vessel inflammation, pancreatic inflammation or muscle cell necrosis.

These are highly serious side effects.

Onset of any of these symptoms indicates that you are seriously allergic to LAMINOX.

You may require urgent medical care or hospitalization.

All of these serious side effects are very rare.

Immediately notify your physician or seek medical attention at the nearest emergency station if one of the following occurs:

- Signs of unexplained persistent nausea, vomiting, abdominal pain, loss of appetite and much tiredness,
- Jaundice of skin or eyeballs, dark urine or pale stools (symptoms of liver disorder),
- Throat pain combined with fever and trembling, Unexpected hemorrhage or bruise development (possible signs of diseases affecting the level of certain blood cell types),
- Anomalous paleness of the skin, mucous cell layer or nail plates, much tiredness or weakness, or respiratory difficulty after effort (possible signs of a disease which affects the level of red blood cells),
- Symptoms including shortness of breath, dizziness, swollen face or throat in particular, hot flashes, cramping abdominal pain and unconsciousness, joint pain, stiffness, pruritus, fever or swollen lymph nodes (possible signs of severe allergic reactions),
- Rash, fever, itching, tiredness, subcutaneous reddish stains / purplish in color (possible signs of blood vessel inflammation),
- Skin problems,

- Severe pain spreading on the back at the upper quadrant of the stomach (possible signs of pancreatitis),
- Unexplained muscular weakness and pain or dark (red -brown) urine (possible signs of muscle cell necrosis).

These are serious symptoms and may require urgent medical intervention.

Immediately inform your physician if any of the following occurs:

Side effects are listed as shown in the following categories:

Very common: May occur at least in 1 of 10 patients,
Common: Less than one in 10 patients, but more than one in 100 patients,
Uncommon: Less than one in 100 patients, but more than one in 1.000 patients,
Rare: Less than one in 1.000 patients,
Very rare: Less than one in 10.000 patients,
Unknown frequency: Few patients unknown with the existing data

Very common:

- Nausea
- Mild gastric pain
- Heartburn
- Diarrhea
- Fullness
- Loss of appetite
- Skin rash
- Pain in the muscles and joints
- Impaired sight

Common:

- Headache

Uncommon:

- Loss or changes of the sense of taste. This is typically rare and returns to the normal state a few weeks after discontinuation of LAMINOX. It may result in loss of appetite and significant weight loss in very few patients. You should notify your physician of any changes in the sense of taste lasting for several days.

Rare:

- Liver problems

Very rare:

- Decrease in certain types of blood cells
- Lupus (an immune system disorder)
- Severe skin reactions
- Allergic reactions
- Hair loss
- Tiredness
- Psoriasis like skin rash
- Worsened psoriasis condition
- Dizziness
- Decreased physical activity
- Numbness – Insensitivity
- Tingling

The following side effects have been also reported:

- Low level of red blood cells
- Severe allergic reactions
- Blood vessel inflammation
- Nasal disorders such as permanent decrease in the smelling sense
- Pancreatitis
- Muscle cell necrosis
- Flu like symptoms (e.g. tiredness, trembling, throat pain and pain in the muscles and joints)

- Fever
- Increase of blood levels of a muscular enzyme (creatine phosphokinase)
- Oversensitivity of the skin to sunlight

Please inform your physician or pharmacist of any side effect not listed in this package leaflet.

5. How to store LAMINOX

Store LAMINOX in its package in areas away from the reach of children. Store at room temperature below 25°C. Protect from light.

Use in concordance with the expiry date.

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

Do not use LAMINOX if you notice any defects in the product and/or package.

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