

Package leaflet: information for the patient**Terbinafină Slavia 10 mg/g cream**

Terbinafine hydrochloride

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

Always use this medicine as directed in this leaflet or as directed by your physician or your pharmacist.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need additional information or advice.
- If you get any adverse reactions, talk to your physician or your pharmacist. This includes any possible adverse reactions not listed in this leaflet. See section 4.
- If after 2 weeks you do not feel better or if you feel worse, you should see a physician.

What is in this leaflet

1. What Terbinafină Slavia is and what it is used for
2. What you need to know before you use Terbinafină Slavia
3. How to use Terbinafină Slavia
4. Possible adverse reactions
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1. What Terbinafină Slavia is and what it is used for

Terbinafină Slavia belongs to the group of antifungal drugs; it works by destroying fungi which cause skin diseases. Terbinafină Slavia is used in the treatment of: tinea pedis, tinea cruris, and tinea corporis. It is also used in the treatment of skin infections with yeasts, such as: candidiasis and pityriasis versicolor.

Tinea pedis occurs only on the foot (usually both feet are affected, but not always), often between the toes. It can also appear at the level of the hollow of the ankle, the sole or in other areas of the the leg. The most common forms are characterized by the production of cracks or peeling of the skin, but also by the appearance of slight swellings, blisters or suppurating ulcers.

Please see your doctor if you have a fungal infection of the nail (fungus in and under the nail), with nails discoloration and changes in their structure (thickened, brittle), because Terbinafină Slavia is not indicated in the treatment of these infections. Tablets containing terbinafine should be used in the treatment of fungal nail infections, which can only be administered with a medical prescription.

Tinea cruris occurs on areas of the body where the skin is folded, especially if they are moist. These areas are: the inguinal region and the inner face of the thighs, the damage being usually bilateral, but frequently, one area is more affected than the other. The infection can spread to the areas between the legs, to the buttocks, or up towards the upper abdomen. The infection can also occur at the level of the breast fold, armpit or other folding areas. The rash that appears on the skin has a smooth edge and may have blisters. It causes itches.

Tinea corporis can appear in any area of the body, but more frequently on the head, neck, face, or arms. Its appearance is usually in the form of circular areas of erythematous rash, but it can appear also in the form of scaly areas and it causes itching.

Cutaneous candidiasis also occurs in areas of the body where the skin is irritated and moist because of its perspiration (for example under the breasts, in the armpits). It usually occurs in elderly or obese patients or those with diabetes. It causes skin redness, itching and scaling.

Pityriasis versicolor appears on the skin in the form of scaly areas that become white spots due to loss of skin pigment. The spots are most obvious during the summer while the surrounding skin areas get tanned. The infection usually occurs on the trunk, neck, arms and can reappear after a few months, especially in case of hot weather and profuse sweating.

If you are not sure about the cause of your infection, please talk to your physician or your pharmacist before using the cream, because they can give you the necessary recommendations.

2. What you need to know before you use Terbinafină Slavia

Do not use Terbinafină Slavia:

- if you are allergic to terbinafine hydrochloride or to any other component of this medicine (listed in section 6).

Warnings and precautions

Before using Terbinafină Slavia, consult your physician or pharmacist.

Terbinafină Slavia is only indicated for administration on the skin. You should not apply it inside the mouth or swallow it. Avoid contact of the cream with your eyes. If the cream comes into contact with your eyes accidentally, wipe it off and wash your eyes vigorously with plenty of cold water.

Terbinafină Slavia with other medicines

Tell your physician or pharmacist if you are taking, have recently taken or may take any other medicines.

Do not apply other medicines on the treated areas.

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 physician or pharmacist for advice before taking any medicine.

There are no clinical data available regarding the use of Terbinafină Slavia in pregnant women. Therefore, excepting the cases where the maternal therapeutic benefit exceeds the possible risk to the fetus, Terbinafină Slavia must not be used during pregnancy; if you are pregnant ask your physician before using Terbinafină Slavia.

Do not use Terbinafină Slavia during breastfeeding, because terbinafine, the active substance in the cream, is excreted in breast milk. Infants should not come into contact with the skin areas on which the cream had been applied, including the one on the breasts.

Driving vehicles and use of machineries

Terbinafină Slavia does not influence the ability to drive vehicles and use machines.

Terbinafină Slavia contains cetostearyl alcohol. It can cause local adverse reactions of the skin (for example, contact dermatitis). At the appearance of skin hypersensitivity reactions, the treatment must be interrupted.

3. How to use Terbinafină Slavia

Adults and teenagers

If the tube is sealed, pierce the seal using the sharp tip on the cap.

- clean and dry the affected skin area and adjacent areas, then wash your hands;
- open the tube and put a small amount of cream on your finger;
- put the cap back on the tube;
- apply enough cream in a thin layer to the affected area and the area around it;
- gently massage the area where you applied the cream;
- wash your hands after touching the infected skin area so that the infection does not spread to other areas or pass the infection on to someone else.

If you are treating an infection that has occurred in folding areas of your body, you can cover the area where you applied the cream with a gauze bandage, especially at night. If you do this, use a new gauze pad every time you apply the cream.

Apply Terbinafină Slavia to the infected areas as follows:

- tinea pedis: 1 administration per day for one week;
- tinea cruris and tinea corporis: 1 administration per day for one week;
- cutaneous candidosis: 1-2 administrations per day for 1-2 weeks;
- pityriasis versicolor: 1-2 administrations per day for 2 weeks.

Use Terbinafină Slavia according to the recommendations in this leaflet, even if the infection seems to be cured after a few days. Infections seem to improve after a few days of treatment, but may recur if the medicine is not applied regularly or the treatment is stopped too soon.

In case of using Terbinafină Slavia, the improvement of the skin condition should appear after a few days; complete healing of the affected skin area is achieved after a period of time of up to 4 weeks (after stopping treatment with Terbinafină Slavia, the improvement process will continue), even if the symptoms disappeared earlier.

If you have not noticed any signs of improvement within 2 weeks of treatment, please contact your physician or pharmacist who will advise you what to do.

For the effectiveness of the treatment, you must keep the affected skin areas clean, washing them with regularity. Dry them carefully, without massaging them energetically, by lightly patting them. Do not scratch the affected area in case it is itchy, because you can cause the injury to worsen and the healing process to slow down or spread of infection.

Because these infections are contagious, you should not lend your towels or clothes to others. To prevent reinfection, they must be washed frequently.

Children under the age of 16

Do not use Terbinafină Slavia in children under the age of 16.

If you use more Terbinafină Slavia than you should

If you or anyone else accidentally swallow a quantity of Terbinafină Slavia, contact your physician who will tell you what to do.

If you forget to use Terbinafină Slavia

If you forget to apply a dose of cream, apply it as soon as you remember and then continue the treatment as recommended. If you remember close to the time of the next dose, just take the dose that should be administered at that time and then continue the treatment as recommended. Do not apply a double dose to make up for the missed dose.

If you stop using Terbinafină Slavia

Use Terbinafină Slavia as recommended. This is important because stopping the treatment too early increases the risk of recurrence of the infection.

If you have any questions regarding this medicine, talk to your physician or pharmacist.

4. Possible adverse reactions

Like all medicines, Terbinafină Slavia can cause adverse reactions, even though they do not occur in all patients.

The following convention has been used for the classification of adverse reactions in terms of frequency:

- very common (they occur in more than 1 in 10 people);
- common (they occur in less than 1 in 10 people);
- uncommon (they occur in less than 1 in 100 people);
- rare (they occur in less than 1 in 1,000 people);
- very rare (they occur in less than 1 in 10,000 people);
- with unknown frequency (it cannot be estimated from the available data).

Skin and subcutaneous tissue disorders

Rare: itching, skin eruptions, bullous eruptions and urticaria, which cause treatment interruption.

Very rare: at the site of application, reddening of the skin, burning sensation, irritation may occur, in which case the treatment discontinuation is rarely indicated.

If any of the adverse reactions become serious or if you notice any adverse reaction not listed in this leaflet, please tell your physician or pharmacist.

Reporting of adverse reactions

If you get any adverse reactions, talk to your physician or pharmacist. These include any possible adverse reactions not listed in this leaflet. Also, you can report adverse reactions directly through the national reporting system, details of which are published on National Agency for Medicines and Medical Devices of Romania web-site <http://www.anm.ro/>.

By reporting adverse reactions, you can help provide additional information about the safety of this medicine.

5. How to store Terbinafină Slavia

Keep this medicine out of the sight and reach of children.

Store at temperatures lower than 25°C, in the original package.

Do not use this medicine after the expiry date which is stated on the package, after EXP. The expiry date refers to the last day of that month.

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 does Terbinafină Slavia contain

- The active substance is terbinafine hydrochloride. Each gram of cream contains 10 mg of terbinafine hydrochloride.
- The other components are: cetostearyl alcohol, vaseline, paraffin oil, polysorbate 80, trolamine, benzyl alcohol, purified water.

What Terbinafină Slavia looks like and contents of the pack

Terbinafină Slavia comes in the form of a homogeneous, white mass.

It is available in a box with one Al tube of 20 g cream.

Marketing authorisation holder and manufacturer

Marketing authorisation holder

S.C. SLAVIA PHARM S.R.L.
44C Theodor Pallady Blvd.
3rd District, Bucharest, Romania

Manufacturer

S.C. SLAVIA PHARM S.R.L.
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3rd District, Bucharest, Romania

For any information regarding this medicine, please contact your local representative of the marketing authorization holder.

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