

Package leaflet: information for the patient**Terbinafină Slavia 250 mg comprimate**

Terbinafine

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

- Keep this leaflet. You may need to re-read it.
 - If you have any additional questions, ask your doctor or pharmacist.
 - This medicine has been prescribed only for you. You must not give it to other people. It can harm them, even if they have the same signs of illness as you.
 - If you experience any side effects, address to your doctor or pharmacist.
- These include any possible side effects not mentioned in this leaflet. See point 4.

What you find in this leaflet:

1. What is Terbinafină Slavia and what is it used for
2. What you need to know before using Terbinafină Slavia
3. How to use Terbinafină Slavia
4. Possible side effects
5. How to store Terbinafină Slavia
6. Contents of the packaging and other information

1. What is Terbinafină Slavia and for what is it used for

Terbinafină Slavia tablets are used for the treatment of fungal infections of fingernails and toenails.

Also, the Terbinafină Slavia tablets are used for the treatment of tinea-type infections (dermatophytoses) of the scalp and hair, groin area and other areas of the body, legs (athlete's foot), as well as for the treatment of yeast infections of the skin.

Terbinafine belongs to a group of medicines called antifungal agents and is used to treat fungal infections of the skin, hair and nails. Administered orally, terbinafine reaches the site of infection in high enough concentrations in order to kill the fungus or stop its growth.

2. What you need to know before using Terbinafină Slavia

Terbinafină Slavia tablets will only be prescribed to you by your doctor. Follow all your doctor's instructions carefully, even if they differ from the general information contained in this leaflet.

Do not use Terbinafină Slavia:

- if you are allergic to terbinafine or any of the other components of this medicine (listed in Point 6)
- if you have or have had hepatic problems of any kind
- if you have renal problems of any kind.

If you are in any of these situations, tell your doctor before using Terbinafină Slavia.

Warnings and precautions

- if you are using other medicines (see Use of other medicines).
- if you have symptoms such as persistent and unexplained nausea, vomiting, stomach pain, loss of appetite,

unusual fatigue; if you notice yellowing of your skin or eyes, your urine becomes unusually dark or your faeces are unusually light in color (signs of hepatic disorders).

- if you have any type of skin problems, such as cutaneous eruption, redness, blistering of the lips, eyes or mouth, peeling of the skin (signs of serious skin reactions).
- if you feel weakened, have unusual bleedings, bruising or frequent infections (signs of sanguine disorders).

If you are in any of these situations, tell your doctor before using Terbinafină Slavia.

Use in the elderly

Terbinafină Slavia tablets can be used by people over the age of 65. If you are over 65 years of age, you will use the same dose as for other adults.

Use in children

Terbinafină Slavia tablets is not recommended for use in children under 2 years of age.

Terbinafină Slavia together with other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including herbal medicines, oral contraceptives (birth control pill).

These include:

- some antibiotics (for example, rifampicin);
- caffeine;
- some antidepressants (for example, desipramine);
- some medicines used in the treatment of heart disorders (for example: propafenone);
- some medicines used in the treatment of high blood pressure (for example: metoprolol);
- some medicines used in the treatment of gastric ulcers (for example, cimetidine);
- some medicines used to treat fungal infections (for example fluconazole, ketoconazole);
- some medicines used to treat cough (for example dextromethorphan);
- ciclosporin, a medicine used to control the immune system to prevent organ transplanted rejection.

Make sure you tell your doctor about all these or any other medicines you are taking.

Terbinafină Slavia with food, drinks and alcohol

You can use Terbinafină Slavia with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or intend to become pregnant, address to your doctor or pharmacist for recommendations before taking this medicine.

Pregnancy

If you are pregnant or think you are pregnant, tell your doctor. Terbinafină Slavia should not be used during pregnancy, unless absolutely necessary. The doctor will discuss with you the possible risks of using Terbinafină Slavia during pregnancy.

Breastfeeding

You must not breastfeed while using Terbinafină Slavia, as it is excreted in breast milk and this thing may harm your child.

Driving vehicles and using machineries

If you feel dizzy while using Terbinafină Slavia tablets, do not drive vehicles or operate machineries.

3. How to use Terbinafină Slavia

Always use Terbinafină Slavia exactly as your doctor has told you. If you have any questions about the

administration of this medicine, address your doctor or pharmacist.

Do not exceed the recommended dose. If you have the impression that the effect of Terbinafină Slavia is too strong or too weak, address your doctor or pharmacist.

Adults

The usual dose for adults and elderly patients is 250 mg terbinafine once a day (one Terbinafină Slavia tablet).

Children

No data are available in children under the age of 2 (usually, weighing less than 12 kg).

Children weighing >40 kg: the recommended dose is one Terbinafină Slavia tablet (250 mg terbinafine), once a day.

How long should you use Terbinafină Slavia

This depends on the type of infection you have, how severe it is and which area of the body is affected. Your doctor will tell you exactly how long you will need to use the tablets.

The normal duration of treatment is as follows:

For tinea-type infections (dermatophytoses) of the legs ("athlete's foot"), Terbinafină Slavia should be used for 2-6 weeks.

For tinea-type infections (dermatophytoses) and ringworm infections, groin infections and of other areas of the body, Terbinafină Slavia should be used for 2-4 weeks.

It is important to take the tablet(s) daily and to continue taking them for as long as your doctor recommends.

This is necessary to make sure that the infection is completely cured and that the chance of it coming back after stopping the treatment is much lower.

Hair and scalp infections

For tinea-type infections (dermatophytoses) of the scalp and hair, the normal duration of treatment is 4 weeks.

Nail infections

Usually, fungal infections of the nails usually take longer time to heal compared to fungal infections of the skin.

For most nail infections, Terbinafină Slavia should be used from 6 to up to 12 weeks.

Fingernail infections

Duration of treatment: in most cases, 6 weeks of treatment are sufficient.

Toenail infections

Duration of treatment: in most cases, 12 weeks are sufficient.

Some patients, with slow nail growth, may require a longer treatment. The doctor will discuss this aspect with you.

If you use more Terbinafină Slavia than you should

If you accidentally use more tablets of Terbinafină Slavia than your doctor prescribed, tell your doctor immediately or go to the emergency department of the nearest hospital. Overdose symptoms include: headache, nausea, chest pain and dizziness.

If you forget to use Terbinafină Slavia

If you forgot to take a Terbinafină Slavia tablet on time, take it as soon as you remember. If less than 4 hours until you need to take your next dose remain, wait and take your next dose at the right time. Do not take a double dose to make up for a missed dose.

If you have any additional questions about this medicine, address your doctor or pharmacist.

4. Possible adverse reactions

Like all medicines, this medicine can cause side effects, although they do not occur to every person. In general, Terbinafină Slavia is well tolerated.

The following side effects may occur:

Some side effects can be serious:

Rarely, Terbinafină Slavia tablets can cause liver problems, in very rare cases liver disorders can be serious.

Serious side effects include a decrease in certain types of blood cells, lupus (an autoimmune disease), serious skin reactions, serious allergic reactions, blood vessels inflammation, pancreas inflammation, or muscle necrosis.

Tell your doctor immediately if:

- you have symptoms such as persistent and unexplained nausea, gastric problems, appetite loss, unusual tiredness or weakness or if
- notice yellowing of the skin or eyes, your urine becomes unusually dark or faecal matter is unusually light in color (possible signs of liver disorders);
- you have a sore throat with fever and chills or if
- you have unexplained bleeding or bruising (possible signs of diseases that affect the number of certain types of blood cells).
- if you notice abnormal skin, mucous membranes or nails pallour, if you have weakness or difficulty breathing on exertion (possible signs of a disorder that affects the red blood cells).
- you have breathing difficulties, dizziness, swelling especially of the face and neck, redness, abdominal pain, cramping and loss of consciousness or if you have symptoms such as joint stiffness, stiffness, rash, fever or swollen/enlarged lymph nodes (possible signs of serious allergic reactions).
- if you have symptoms such as transitory cutaneous reactions, fever, itching, tiredness, or if you notice the appearance of red-purple spots under the surface of the skin (possible signs of inflammation of the blood vessels).
- you have any type of serious skin problems.
- if you suffer from severe pain in the upper part of the stomach, which radiates to the back (possible signs of pancreas inflammation).
- if you suffer from unexplained muscle weakness and pain or have dark (reddish-brown) urine (possible signs of muscle necrosis).

Very common (affects more than 1 user in 10)

- feeling of fullness, loss of appetite, indigestion, nausea, chest pain, diarrhea. If the diarrhea lasts for several days, contact your doctor, because it may be necessary to change the treatment scheme;
- cutaneous transitory eruption, hives;
- joint pain and muscle pain.

Common (affects 1 to 10 users in 100)

- headaches.

Uncommon (affects 1 to 10 users in 1,000)

- taste disturbances up to the loss of taste; these disorders are transient and disappear after stopping the treatment. In some patients, it can cause a reduction in appetite and significant weight loss. Tell your doctor if the change in taste lasts for several days.

Rare (affects 1 to 10 users in 10,000)

- hepatic disorders

Very rare (affects less than 1 in 10,000 users)

Decrease in the number of certain types of blood cells, lupus (an autoimmune disease), serious skin reactions, allergic reactions, hair loss, dizziness, reduced physical sensitivity, numbness and itching.

The following side effects have also been reported:

Low red blood cell count, severe allergic reactions, inflammation of blood vessels, impaired sense of smell, including permanent loss of smell, pancreas inflammation, muscle necrosis, flu-like symptoms (eg, tiredness, chills, joint or muscle pain), fever, increase in the level of a muscle enzyme in the blood (creatine-phosphokinase), increased skin sensitivity to sun exposure.

Frequency not known: psoriasis worsening (scaly skin disease), fatigue, serious skin reactions (e.g. acute generalized exanthemic pustulosis).

Adverse reaction reporting

If you experience any side effects, contact your doctor or pharmacist. These include any side effects not mentioned in this leaflet. You can also report adverse reactions directly through the national reporting system, the details of which are published on the website of the National Agency for Medicines and Medical Devices

<http://www.anm.ro/>. By reporting side effects, 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 below 25°C, in the original packaging.

Do not use after the expiration date written on the package, after EXP. The expiry date refers to the last day of the respective month.

Do not throw any medicine into water or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the packaging and other information

What does Terbinafină Slavia contain

- The active substance is terbinafine. One tablet contains 250 mg of terbinafine (as terbinafine hydrochloride).
- The other components are: microcrystalline cellulose, corn starch, colloidal anhydrous silica, hypromellose, talcum, magnesium stearate.

What does Terbinafină Slavia look like and the packaging contents

The medicine is packed in boxes with 2 blisters of 7 tablets each.

It is presented in the form of flat tablets, white to yellowish-white, with a 11 mm diameter.

Marketing authorization holder and manufacturer

Marketing authorization holder

S.C. Slavia Pharm S.R.L.
44C Theodor Pallady Bvd,
3rd District, Code 032266, Bucharest, Romania

Manufacturer

S.C. Slavia Pharm S.R.L., 44C Theodor Pallady Bvd, 3rd District, Bucharest, Romania

This leaflet was revised in July 2017.

Detailed information on this medicine is available on the website of the National Agency for Medicines and Medical Devices <http://www.anm.ro/>