

PACKAGE LEAFLET: INFORMATION FOR THE USER

Terbinafine Aurobindo 125 mg, tablets
Terbinafine Aurobindo 250 mg, tablets
terbinafine

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

Keep this leaflet. You may need to read it again.

Do you have any questions? Please contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.

Do you experience a lot of side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Please contact your doctor or pharmacist.

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1. WHAT IS TERBINAFINE AUROBINDO AND WHAT IS IT USED FOR?

Terbinafine Aurobindo belongs to a group of medicines called antifungals. It is used to treat fungal infections of the skin (for example, between the fingers and toes) and nails.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAREFUL WITH IT?

When should you not use this medicine?

you are allergic to terbinafine or any of the ingredients in this medicine. You can find these ingredients in section 6

if you have severe kidney problems

if you have severe liver problems.

When should you be extra careful with this medicine?

if you have liver problems or a disease that can damage your liver

if you have psoriasis (a skin disease with red patches on the skin covered with scales)

if you have kidney problems

if you develop a severe reduction in the number of white blood cells, which increases the risk of infections (agranulocytosis) or a severe illness with blistering on the skin (toxic epidermal necrolysis). You should stop using this medicine and contact your doctor immediately if you experience these side effects, which are known to occur very rarely (see section 4)

if you have skin conditions with red dry patches on the nose and cheeks (skin and lupus erythematosus).

Contact your doctor if any of the above warnings apply to you or have applied to you in the past.

Are you using any other medicines?

Are you using any other medicines besides Terbinafine Aurobindo, have you recently done so, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines you can obtain without a prescription.

the antibiotic rifampicin (lowers the concentration of this medicine in your blood)
cimetidine (a medicine for stomach complaints and heartburn) increases the concentration of this medicine in your blood
antidepressants (medicines for, among other things, depressive mood) including tricyclic antidepressants, SSRIs (selective serotonin reuptake inhibitors) or MAO inhibitors (MAO inhibitors)
beta-blockers (a certain group of medicines for high blood pressure, certain heart conditions, and increased eye pressure) or antiarrhythmics (medicines for heart rhythm disorders) for heart problems
oral contraceptives (the pill). Female patients may experience irregular menstrual cycles or bleeding between periods
medicines to treat heart problems (such as propafenone, amiodarone)
cyclosporin (medicine used to prevent organ or tissue rejection after a transplant or to treat certain skin conditions, such as psoriasis and eczema, or to treat rheumatoid arthritis)
tolbutamide for diabetes
triazolam for relieving anxiety and/or sleep problems
terfenadine for hay fever or other allergies
medicines for the treatment of fungal infections (such as fluconazole, ketoconazole)
caffeine.

Note: it is possible that you know the above medicines by another name. Always read the package leaflet of the medicines you are already using carefully before using this medicine. Contact your doctor or pharmacist if you are using any of the aforementioned medicines.

What should you pay attention to with food and drink?

The use of food or drink does not affect the treatment with this medicine.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Do not use this medicine unless your doctor deems it necessary. If you become pregnant while being treated with this medicine, you should contact your doctor as soon as possible.

Ask your doctor or pharmacist for advice before using any medicine.

Driving and using machines

Some people have reported feeling dizzy while using this medicine. If you feel this way, you should not drive or operate machines.

Terbinafine Aurobindo contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist, or nurse has told you. If you are unsure about the correct use, contact your doctor, pharmacist, or nurse.

Dosage

Adults

The prescribed dose depends on the type and severity of the infection. The usual dosage is 250 mg Terbinafine Aurobindo per day. Swallow the tablet whole with a glass of water. The tablets can be taken with or without food. If you have kidney problems, the doctor may halve the recommended dose.

Duration of treatment

Your doctor will tell you how long your treatment with this medicine will last.

for general fungal infections of the skin, the treatment will likely last 4 weeks
the treatment of skin infections in the groin or on the body usually lasts 2 to 4 weeks;
the treatment of infections on the feet lasts 2 to 6 weeks
for nail infections, a treatment of 6 weeks to 3 months may be sufficient, but for toenail infections, a treatment of 6 months or longer is often needed.

Sometimes the symptoms of infection only disappear completely a few weeks after ending the treatment and the healing of the infection.

Use in children and adolescents up to 18 years

This medicine is not recommended for children and adolescents up to 18 years.

Have you taken too much of this medicine?

If you, or someone you know, have taken more tablets than you should, contact your doctor or the emergency department of the nearest hospital. Take this leaflet and some tablets with you, so the doctor knows what you have taken. You may experience symptoms such as dizziness, nausea, headache, or stomach pain.

Have you forgotten to take this medicine?

If you have forgotten to take this medicine at the usual time, take the tablet as soon as possible. Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

Do not stop using this medicine without consulting your doctor, even if the symptoms of infection improve.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Stop using the tablets and contact your doctor:

if you experience symptoms of angioedema/anaphylaxis, such as:

- swelling of the face, tongue, or throat
- difficulty swallowing
- hives
- shortness of breath
- fainting

if you develop skin reactions such as welts, blisters, or a progressive skin rash

if you have impaired liver function. Symptoms include: jaundice, itching, unexplained and persistent nausea, fatigue, vomiting, dark-colored urine, light-colored stools, and abdominal pain.

The following side effects were observed:

Very common (occur in more than 1 in 10 users)

decreased appetite

stomach pain, bloating, diarrhea, indigestion, nausea

joint pain (arthralgia) and muscle pain (myalgia)

rash, redness of the skin with itching and hives (urticaria).

headache

Common (occur in less than 1 in 10 users)

depression

disturbance or loss of taste. This usually gradually disappears once you stop taking this medication. Very rare cases of prolonged taste disorders have been reported, sometimes leading to reduced food intake and significant weight loss.

dizziness

visual impairment

fatigue

Sometimes (occur in less than 1 in 100 users)

tinnitus

tingling sensation (paresthesia), numbness (hypesthesia)

weight loss

decrease in the number of red blood cells (anemia).

Increased sensitivity of your skin to sunlight.

Rarely (occur in less than 1 in 1,000 users)

increased concentration of liver enzymes in the blood.

abnormal liver function, including liver inflammation (hepatitis) and jaundice (yellowing of the skin and eyes), bile duct obstruction (cholestasis), abnormal liver function test results, liver dysfunction (mainly cholestatic in nature).

Very rarely (occur in less than 1 in 10,000 users)

reduction in the numbers of different types of blood cells; this can lead to an increased risk of serious infections and bleeding and can also cause shortness of breath and fatigue (agranulocytosis, neutropenia, thrombocytopenia, pancytopenia)
systemic lupus erythematosus, a condition that can cause a wide range of symptoms such as joint pain, kidney problems, skin rash, and fever
Stevens-Johnson syndrome (a serious disease with blistering of the skin, mouth, eyes, and genitals)
hair loss
toxic epidermal necrolysis (a serious disease with blistering and peeling of the skin)
severe allergic reactions causing swelling of the face and throat (angioedema)
psoriasiform eruptions or exacerbation of psoriasis.
rash with scaling or peeling of the skin, hair loss. Severe skin reactions with blistering or peeling of the skin (e.g., erythema multiforme exudativum [EME], Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalized exanthematous pustulosis [AGEP]).

Not known (cannot be determined from the available data):

allergic reactions (including anaphylaxis)
loss of smell (anosmia) which may be permanent, • blurred vision, reduced visual acuity.
hearing loss (hypoacusis)
inflammation of the blood vessels (vasculitis)
inflammation of the pancreas with symptoms of severe pain in the upper abdomen radiating to the back, nausea, and vomiting (pancreatitis)
breakdown of muscle tissue with symptoms of muscle cramps, fever, and reddish-brown discoloration of the urine (rhabdomyolysis) flu-like symptoms or fever
skin rash accompanied by an increase in certain cells in the blood (eosinophilia).

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. This can be found on the box and the blister pack after "Exp.". It includes a month and a year. The last day of that month is the expiry date.

Store in the original packaging to protect from light.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What substances are in this medicine?

The active substance in this medicine is terbinafine.

Each tablet contains 125 mg terbinafine (as terbinafine hydrochloride).

Each tablet contains 250 mg terbinafine (as terbinafine hydrochloride).

The other substances in this medicine are: microcrystalline cellulose, sodium starch glycolate (type A), colloidal anhydrous silica, hypromellose, and magnesium stearate.

What does Terbinafine Aurobindo look like and how much is in a package?

Tablets.

125 mg:

White to off-white, round, uncoated, biconvex, beveled edge tablets with 'D' on one side and '56' on the other side.

250 mg:

White to off-white, round, uncoated, biconvex, beveled edge tablets with a score line and with 'D' on one side and '74' on the other side. The tablets can be divided into two equal halves.

Terbinafine Aurobindo tablets are available in PVC/PVDC/Aluminum blister packaging.

Packages of 6, 7, 8, 10, 12, 14, 20, 28, 30, 42, 50, 56, 60, 84, 90, 98, 100, 250, and 500 tablets.

Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Aurobindo Pharma B.V.

Baarnsche Dijk 1

3741 LN Baarn

Netherlands

Manufacturer

APL Swift Services (Malta) Limited

HF 26, Hal Far Industrial Estate

Birzebbugia BBG 3000

Malta

This product is registered under

Terbinafine Aurobindo 125 mg, tablets: RVG 106095

Terbinafine Aurobindo 250 mg, tablets: RVG 106096

This medicine is registered in the EEA member states under the following names

France: TERBINAFINE ARROW GENERIQUES 250 mg, scored tablet

Germany: Terbinafin Aurobindo 250 mg Tablets

Italy: Terbinafina Aurobindo Pharma Italia 250 mg tablets

Malta: Terbinafine Aurobindo 125 mg/250 mg tablets

Netherlands: Terbinafine Aurobindo 125/250 mg, tablets

Poland: Terbinafine Aurobindo

Spain: Terbinafine Aurobindo 250 mg tablets

United Kingdom: Terbinafine 250 mg tablets

This leaflet was last approved in January 2022

Transtoyou