

Terbinafine Rowa 250 mg Tablets

terbinafine

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Terbinafine Rowa is and what it is used for
2. What you need to know before you take Terbinafine Rowa
3. How to take Terbinafine Rowa
4. Possible side effects
5. How to store Terbinafine Rowa
6. Contents of the pack and other information.

1 What Terbinafine Rowa is and what it is used for

Terbinafine Rowa 250 mg Tablets contains terbinafine, a substance which belongs to a group of medicines called antifungal agents, which inhibit the growth of fungi. This medicine is used to treat a number of fungal infections of the skin and nails.

2 What you need to know before you take Terbinafine Rowa

Do not take Terbinafine Rowa:

- If you are allergic to terbinafine or any of the other ingredients of this medicine (listed in section 6).
- If you have or have had any liver problems

Warnings and precautions

Talk to your doctor or pharmacist before taking Terbinafine Rowa.

- If you have ever had liver or kidney problems
- If you have psoriasis
- If you have systemic lupus erythematosus (SLE)
- If you have serious skin reactions.

Children and adolescents

Terbinafine Rowa tablets are not recommended for use in children or adolescents.

Other medicines and Terbinafine Rowa

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including oral contraceptives and medicines obtained without prescription.

Some other medicines may interact with Terbinafine Rowa 250 mg Tablets. These include:

- rifampicin - used to treat infections
- cimetidine – used to treat stomach problems such as indigestion or stomach ulcers
- ciclosporin – used to control your body's immune system after a transplant
- anti-depressants – including tricyclic anti-depressants such as desipramine, SSRIs (selective serotonin reuptake inhibitors), or MAOIs (monoamine oxidase inhibitors)
- oral contraceptives (as irregular periods and breakthrough bleeding may occur in some female patients)
- beta-blockers or anti-arrhythmics – for treating heart problems, such as metoprolol, propafenone or amiodarone
- warfarin, a medicine used to thin your blood
- medicines to treat heart problems (e.g. propafenone, amiodarone)
- anti-fungals – used to treat fungal infections such as fluconazole or ketoconazole
- dextromethorphan – used in some cough medicines
- caffeine – used in some pain killers or cold remedies.

You should have blood tests before and during treatment with Terbinafine Rowa 250 mg Tablets to monitor your liver function.

Terbinafine Rowa with food and drink

The tablets can be taken with or without food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Terbinafine passes into mother's milk.

Therefore, you should not breast-feed during treatment with this medicine.

Driving and using machines

Some people have reported feeling dizzy or giddy while they are taking Terbinafine Rowa 250 mg Tablets. If you feel like this you should not drive or operate machinery.

Information about sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3 How to take Terbinafine Rowa

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take the number of tablets as instructed by your doctor. He/she will decide what dose you need.

The recommended dose is one tablet (250 mg) taken once a day.

Use in children and adolescents

Your medicine is not recommended for use in children and adolescents (<18 years) due to lack of experience in this age group.

Swallow the whole tablet with some water. Do not chew the tablet. The tablet may be taken with or without food.

The tablet can be divided into equal doses.

Skin infections: treatment takes between 2 to 6 weeks

Onychomycosis (fungal infection of the nail)

Treatment usually lasts between 6 weeks and 3 months, although some patients with toenail infections may need to be treated for 6 months or longer.

Do not change the dose or stop the treatment without consulting your doctor.

If you take more Terbinafine Rowa than you should

If you accidentally take an excessive number of tablets, immediately consult your doctor. The main symptoms of acute intoxication are nausea, stomach pain dizziness or headache. If any of these symptoms or any other abnormal side effects occur, consult your doctor immediately.

If you forget to take Terbinafine Rowa

If you miss taking a Terbinafine Rowa 250 mg Tablet, do not worry. Take it as soon as you remember.

Take your next tablet at the usual time, then carry on as normal until you have finished all the tablets. It is important that you finish all the tablets you have been given unless your doctor tells you to stop taking them.

If you stop taking Terbinafine Rowa

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

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

It is very important that you **immediately tell your doctor:**

- Yellowing of your skin or eyes. Unusually dark urine or pale faeces, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness (this may indicate liver problems), increase in liver enzymes which may be noted on a blood test result
- Severe skin reactions including rash, light sensitivity, blistering or wheals
- Weakness, unusual bleeding, bruising, abnormal pale skin, unusual tiredness, or weakness or breathlessness on exertion or frequent infections (this may be a sign of blood disorders)
- Difficulty breathing, dizziness, swelling mainly of the face and throat, flushing, crampy abdominal pain, stiffness, rash, fever or swollen/enlarged lymph nodes (possible signs of severe allergic reactions)
- Symptoms such as rash, fever, itching, tiredness or if you notice appearance of purplish spots under the skin surface (signs of blood vessel inflammation)
- Severe upper stomach pain which spreads to the back (possible signs of pancreas inflammation)
- Unexplained muscle weakness or pain, or dark (red-brown) urine (possible signs of muscle breakdown).

The very common (may affect up to 1/10 people) side effects are:

- Stomach problems such as loss of appetite, ache, indigestion, feeling bloated or sick
- Diarrhoea
- Itching, rash or swelling
- Pains in the muscles and joints.

The common (may affect up to 1/100 people) side effects are:

- Headache.

The following side effects have been reported for Terbinafine Rowa 250 mg Tablets:

Uncommon (may affect up to 1 in 100 people):

- Taste loss and taste disturbance. This usually disappears within several weeks after you stop taking the medicine. However, a very small number of people, (less than 1 in 10,000), have reported that the taste disturbance lasts for some time and, as a result, they go off their food and lose weight. There have also been reports of some

people experiencing anxiety or symptoms of depression as a result of these taste disturbances.

Rare (may affect up to 1 in 1,000 people):

- Feeling unwell, dizzy
- Numbness or tingling.

Very rare (may affect up to 1 in 10,000 people):

- Feeling tired
- Decrease in the number of some blood cells. You may notice that you seem to bleed or bruise more easily than normal, or you may catch infections easily and these might be more severe than usual
- Psoriasis like skin eruptions, or worsening of any psoriasis including a rash or eruption of small pus containing blisters
- Vertigo
- Hair loss.

The following side effects have been reported:

Signs of blood disorders: weakness, unusual bleeding, bruising or frequent infections

Disorders of sense of smell which may be permanent, impaired hearing, hissing and/or ringing in the ears, flu like symptoms, increase in blood of a muscle enzyme called creatine phosphokinase (may be found on a blood test), reduced or blurred vision.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

Reporting of side effects

If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa, Pharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Terbinafine Rowa

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

This medicine does not require any special storage conditions

Do not use this medicine after the expiry date which is stated on the outer carton and on the blister. 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 to protect the environment.

6 Contents of the pack and other information

What Terbinafine Rowa contains

- The active substance is terbinafine. Each tablet contains 250 mg of terbinafine (as hydrochloride).
- The other ingredients are Sodium Starch Glycolate (type A), Cellulose Microcrystalline (E460), Hypromellose (E464), Silica Colloidal Anhydrous and Magnesium Stearate (E572).

What Terbinafine Rowa looks like and contents of the pack

This medicine is white oblong scored tablets presented in packs of 14, 28 and 98 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Rowa Pharmaceuticals Ltd.
Newtown
Bantry
Co Cork
Ireland.

Manufacturer:

LABORATORIOS LICONSA, S.A.
Av. Miralcampo, N^o 7, Polígono Industrial
Miralcampo 19200 Azuqueca de Henares
(Guadalajara)
SPAIN.

This medicinal product is authorised in the Member States of the EEA under the following names:

Portugal:	Terbinafina Liconsa 250 mg Comprimidos
Denmark:	Terbinafin Medical Valley
Estonia:	Terbinafine Liconsa
Hungary:	Terbinafin 250 mg tableta
Iceland:	Terbinafin Medical Valley 250 mg töflur
Ireland:	Terbinafine Rowa 250 mg tablets
Luxembourg:	Terbinafine Liconsa 250 mg Comprimé
The Netherlands:	Terbinafine Xiromed 250 mg tabletten
Slovenia:	Terbinafin Liconsa 250 mg tablete
Sweden:	Terbinafin Medical Valley 250 mg Tablett

This leaflet was last revised in: July 2022.