**Package leaflet: Information for the patient**

**Ternaf 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 Ternaf is and what it is used for

Terbinafine, the active ingredient in Ternaf, is an antifungal medicine.

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

## 2. What you need to know before you take Ternaf

**Do not take Ternaf**
- if you are allergic to terbinafine or any of the other ingredients of this medicine (listed in section 6)
- if you have severe hepatic impairment.

**Warnings and precautions**
Talk to your doctor before taking Ternaf if anything of the following applies to you:
- any problems with your kidneys or liver
- you have psoriasis
- you have lupus erythematosus (an autoimmune disease).

Your doctor should test your liver function before you start taking Ternaf and every 4 to 6 weeks during treatment.

**Children and adolescents**
Ternaf is not recommended for use in childen.

**Other medicines and Ternaf**
Some medicines can interfere with your treatment. Tell your doctor if you are taking any of the following:
- Rifampicin for infections
- Cimetidine for gastric problems such as indigestion or ulcer
- Certain antidepressants including tricyclic antidepressants like desipramine, SSRIs (selective serotonin reuptake inhibitors), or certain MAOIs (monoamine oxidase inhibitors type B)
- Some medicines used to treat fungal infections (such as fluconazole, ketoconazole)
- Dextromethorphan, to treat cough

- Oral contraceptives (as irregular periods, breakthrough bleeding, intermenstrual bleeding and absence of a menstrual period may occur in some female patients)
- Certain beta-blockers (medicines for certain heart or blood vessel problems with active substance names ending in "-lol" such as metoprolol) or drugs that are used to treat abnormal heart rhythms (anti-arrhythmics), such as propafenone, amiodarone
- Caffeine
- Ciclosporin for immune suppression
- Warfarin, a medicine used to thin your blood.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

**Pregnancy and breast-feeding and fertility**
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.

Since clinical experience in pregnant women is very limited, Ternaf should not be used during pregnancy, unless your doctor has explicitly advised you to.

Ternaf should not be used during breast-feeding, since the active compound terbinafine passes into breast milk and might harm your baby.

**Driving and using machines**
Some people have reported feeling dizzy while they are taking Ternaf. If you feel like this you should not drive or operate machinery.

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

## 3. How to take Ternaf

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

**The recommended dose for adults**, including older patients is **1 tablet once a day**.

- For **skin** infections continue taking the tablets for **2 to 6 weeks**.
- For **nail** infections treatment usually lasts for between **6 weeks and 3 months**, although some patients with **toenail** infections need to be treated for **6 months or longer**.

**Mode of use**
Swallow the tablets whole with a glass of water, preferrably at the same time each day.
The tablets can be taken prior to or after meals.

**If you take more Ternaf than you should**
If you take too many Ternaf tablets at once, you might experience headache, nausea, pain in the upper stomach and dizziness. Tell your doctor or hospital casualty department as soon as possible. Take your medicine pack with you so that people can see what you have taken.

**If you forget to take Ternaf**
If you miss taking a Ternaf tablet, do not worry. Take it as soon as you remember. However, if it is almost time for your next dose, wait and take your next tablet at the usual time. Then carry on as normal. Do not take a double dose to make up for a forgotten tablet.

**If you stop taking Ternaf**
You should do this only after consulting your doctor. If this was not possible, you should inform your doctor without delay, so that he/she can decide with you about further action.

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.

**Some side effects can be serious**.
**Tell your doctor immediately** if you notice any of the following rare or very rare symptoms:
- Yellowing of your skin or eyes, unusually dark urine or pale faeces, unexplained persistent nausea, stomach problems, right upper abdominal pain, loss of appetite, unusual tiredness or weakness (this may indicate liver problems)
- Severe skin reactions including rash, light sensitivity, blistering, peeling or wheals
- Symptoms like rash in the face, fever, feeling unwell or tired, joint or muscle pain (possible signs of lupus erythematosus, an autoimmune disease)
- Serious allergic reaction which may cause difficulty in breathing, dizziness, flushing, crampy abdominal pain, stiffness, rash, swelling mainly of the face or throat, fever or swollen/enlarged lymph nodes
- Unusual bleeding, bruising, abnormal pale skin, unusual tiredness or weakness or breathlessness on exertion, sore throat with fever and shivering or frequent infections (this may be a sign of blood disorders)
- Symptoms such as rash, fever, itching, tiredness or if you notice appearance of purplish-red spots under the skin surface (possible signs of blood vessel inflammation)
- Severe upper stomach pain which spreads to the back (possible signs of pancreas inflammation)
- Unexplained muscle weakness and pain, or dark (red-brown) urine (possible signs of muscle breakdown).

**The following side effects have been reported with terbinafine tablets**

**Very common,** affects more than 1 per 10 users
- Headache
- Indigestion
- Nausea
- Stomach-ache
- Diarrhoea
- Feeling bloated
- Loss of appetite
- Itching, rash or swelling
- Pains in the muscles and joints.

**Common**, affects 1 to 10 per 100 users
- Depression
- Taste disturbances and taste loss
  This usually disappears slowly within several weeks when you stop taking the medicine. However, very rarely taste disturbance or taste loss can persist for a longer period.
- Problems with your eye-sight
- Feeling dizzy or tired.

**Uncommon**, affects 1 to 10 per 1,000 users
- Decrease in the number of red blood cells
- Anxiety (with symptoms such as sleep disturbances, fatigue, loss of energy or diminished ability to think or concentrate)

- Numbness or tingling
- Ringing or noise in the ears in the absence of sound (tinnitus)
- Increased sensitivity of skin to sun
- Fever
- Weight loss due to taste disturbances.

**Rare**, affects 1 to 10 per 10,000 users
- Liver problems like liver failure, inflammation of the liver, yellowing of your skin or eyes, increase of liver enzymes in the blood.

**Very rare**, affects less than 1 per 10,000 users
- Decrease in the number of certain blood cells
- Lupus erythematosus (an autoimmune disease)
- Serious skin reactions
- Allergic reactions
- Hair loss
- Skin condition that causes skin cells to grow too quickly, resulting in thick, white, silvery, or red patches of skin (Psoriasis-like skin eruptions, worsening of psoriasis)
- Liver failure, with subsequent liver transplant or death. In the most of these cases had serious underlying diseases.

**Frequency not known**, frequency cannot be estimated from available data
- Severe allergic reaction (anaphylactic reaction, serum sickness-like reaction)
- Decreased hearing, impaired hearing
- Blurred vision, reduced visual acuity
- Inflammation of blood vessels
- Smell disorders including permanent loss of smell
- Depressive symptoms (e.g. depressed mood) due to taste disturbances
- Inflammation of the pancreas
- Drug rash with increase of certain blood cells (eosinophilia) and inflammation of internal organs called "Drug rash with eosinophilia and systemic symptoms" [DRESS])
- pathological process associated with severe cellular trauma in muscles, leading to cell death (muscle necrosis) named rhabdomyolysis or increased muscle enzyme in blood (creatine phosphokinase)
- Flu-like symptoms, such as tiredness, chills, sore throat, joint or muscle aching.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Ternaf

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

Do not use this medicine after the expiry date which is stated on the carton or blister/tablet container after EXP. The expiry date refers to the last day of that month.

Blister: Keep the blisters in the outer carton in order to protect from light.

Tablet container: Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater. 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 Ternaf contains**

- The active substance is terbinafine
  Each tablet contains 250 mg terbinafine as terbinafine hydrochloride.
- The other ingredients are: sodium starch glycolate (Type A), hypromellose, silica colloidal anhydrous, potato starch, magnesium stearate.

**What Ternaf looks like and contents of the pack**
White or almost white, round, scored on both sides, convex tablets, coded “TER 250” on one side packed in blisters/tablet containers.

Pack sizes: 8, 10, 14, 20, 28, 30, 42, 56, 98 and 100 tablets

The tablet can be divided into equal doses.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturers**
**Marketing Authorisation Holder**
Rowex Ltd., Bantry, Co. Cork, Ireland.

**Manufacturers**
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.
Lek S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.
Lek Pharmaceuticals d.d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.
Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220, Slovenia.
Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.

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

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|---|---|
| Germany : | Terbinafin HEXAL 250 MG Tabletten |
| Denmark : | Terbinafin “Hexal" |
| Estonia : | Terbinafine Sandoz 250 mg |
| Finland: | Terbinafin HEXAL 250 mg tabletti |
| Hungary: | Terbinafin HEXAL 250 MG tabletta |
| Ireland: | Ternaf 250 mg Tablets |
| Italy: | TERBINAFINA HEXAL |
| Netherlands | Terbinafine Sandoz 250 mg, tabletten |
| Norway: | Terbinafin Hexal 250 mg tabletter |
| Portugal: | Terbinafina Sandoz 250 mg Comprimidos |
| Sweden: | Terbinafin Hexal 250 mg tabletter |

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