

TERBICIP 250 MG TABLET

Terbinafine Tablets 250 mg

What is in this leaflet

1. What Terbicip tablets are used for
2. How Terbicip tablets works
3. Before you use Terbicip tablets
4. How to use Terbicip tablets
5. While you are using it
6. Side effects
7. Storage and Disposal of Terbicip tablets
8. Product Description

What Terbicip tablets are used for

Terbinafine, the active ingredient in Terbicip tablets, is an antifungal medicine.

Terbicip is indicated in the following conditions:

- Fungal infections of the skin, including the treatment of tinea corporis, tinea cruris, tinea pedis, and yeast infections of the skin caused by the genus *Candida* (e.g., *Candida albicans*) where oral therapy is generally considered appropriate, owing to the site, severity or extent of the infection.
- Tinea capitis
- Onychomycosis (fungal infection of the nails) caused by dermatophyte fungi.

How Terbicip tablets works

Terbinafine is an allylamine which has a broad spectrum of antifungal activity. At low concentrations terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi. The activity versus yeasts is fungicidal or fungistatic depending on the species.

Terbinafine interferes specifically with fungal sterol biosynthesis at an early step. This leads to a deficiency in ergosterol and to an intracellular accumulation of squalene, resulting in fungal cell death. Terbinafine acts by inhibition of squalene epoxidase in the fungal cell membrane. The enzyme squalene epoxidase is not linked to the cytochrome P450 system.

When given orally, the drug concentrates in skin at levels associated with fungicidal activity.

Before you use Terbicip tablets

- When you must not use it if

- you think you may be allergic to terbinafine or to any of the other ingredients of Terbicip Tablets. (see section *Ingredients*).
- you have or have had any liver problems
- you are breast-feeding

- Before you start to use it

You should also ask yourself these questions before taking Terbicip Tablets. If the answer to any of these questions is YES, tell your doctor or pharmacist because Terbicip Tablets might not be the right medicine for you.

- Are you pregnant or trying to become pregnant?
- Do you have any problems with your kidneys or liver?
- Do you have psoriasis?
- Do you have systemic lupus erythematosus (SLE)?
- Do you have rash due to a high level of a specific type of white blood cells?

Children should not normally be given Terbicip Tablets.

TERBICIP 250 MG TABLET

Terbinafine Tablets 250 mg

- Taking other medicines

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
- Antidepressants including tricyclic antidepressants, 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 heart problems
- Warfarin, a medicine used to thin your blood
- Medicines to treat heart problems (eg propafenone, amiodarone)
- Ciclosporin, a medicine used to control your body's immune system in order to prevent rejection of transplanted organs
- Medicines used to treat fungal infections (eg fluconazole, ketoconazole)
- Medicines used to treat cough (eg dextromethorphan)
- Caffeine

Always tell your doctor about all the medicines you are taking. This means medicines you have bought yourself as well as medicines on prescription from your doctor.

You should have blood tests before and during treatment with Terbicip Tablets to monitor your liver function.

How to use Terbicip tablets

- How much to use

Children:

No data are available in children under 2 years of age (usually < 12 kg)

Children weighing 20-40 kg:
Half tablet of Terbinafine 250 mg once a day.

Children weighing >40 kg:
one tablet of Terbinafine 250 mg once a day.

Adults

One tablet of Terbinafine 250 mg once a day.

- When to use it

The duration of treatment varies according to the indication and the severity of the infection.

Skin Infections

Tinea pedis (interdigital, plantar/moccasin type):

2 to 6 weeks.

Tinea corporis/cruris:

2 to 4 weeks

Cutaneous candidiasis:

2 to 4 weeks

Complete resolution of the signs and symptoms of infection may not occur until several weeks after mycological cure.

Hair and Scalp Infections

Recommended duration of treatment.

TERBICIP 250 MG TABLET

Terbinafine Tablets 250 mg

Tinea capitis:

4 weeks

Tinea capitis occurs primarily in children.

Onychomycosis

For most patients the duration of successful treatment is 6-12 weeks.

Fingernail onychomycosis

6 weeks of therapy is sufficient for fingernail infections in most cases.

Toenail onychomycosis

12 weeks of therapy is sufficient for toenail infections in most cases.

Some patients with poor nail outgrowth may require longer treatment. The optimal clinical effect is seen some months after mycological cure and cessation of treatment. This is related to the period required for the outgrowth of healthy nails.

- If you forget to use it

If you miss taking a Terbicip 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 use too much (overdose)

All tablets can be risky if you take too many. If you take too many Terbicip Tablets at once, 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.

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

While you are using it

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

Side effects

Terbicip tablets are suitable for most people, but, like all medicines, they can sometimes cause side effects. Any side effects are usually mild or moderate and don't last for too long.

Some side effects can be serious

Stop taking the tablets and tell your doctor immediately if you notice any of the following rare symptoms:

- 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 most common side effects are:

- Headache

TERBICIP 250 MG TABLET

Terbinafine Tablets 250 mg

- 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 side effects listed below have also been reported.

Up to 1 in 100 people have experienced:

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.

Up to 1 in 1,000 people have experienced:

- Feeling unwell, dizzy
- Numbness or tingling

Up to 1 in 10,000 people have experienced

- 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
- Onset or worsening of a condition called lupus (a long-term illness with symptoms including skin rash and pain in the muscles and joints)

The following have also 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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines).

By reporting side effects you can provide more information on the safety of this medicine.

Storage and Disposal of Terbicip Tablet

- Storage

Store below 30°C. Protect from light.

Keep all medicines out of the reach and sight of children.

Do not take the tablets after their expiry date which is printed on the outside of the pack.

- Disposal

Do not throw them away with your normal household water or waste. This will help to protect the environment.

TERBICIP 250 MG TABLET

Terbinafine Tablets 250 mg

Product Description

- What it looks like

White, circular, biconvex tablets with 'TF' debossed on one side and score line on the other side.

Date of Revision

13/10/2023

Serial Number

NPRA (R2/1)230925/1147

- Ingredients

- *Active ingredient(s)*

Terbinafine Hydrochloride equivalent to Terbinafine 250 mg

- *Inactive ingredients*

Microcrystalline cellulose
Sodium Starch Glycolate (Primogel)
Hypromellose E-15(HPMC E15)
Magnesium Stearate
Colloidal Anhydrous Silica (Aerosil)

- MAL Number

MAL11110010AZ

Manufacturer

CIPLA LTD.
Plot L-139 to L-146,
Verna Industrial Estate,
Verna – Goa, India.

Product Registration Holder

CIPLA MALAYSIA SDN BHD
Suite 1101, Amcorp Tower,
Amcorp Trade Centre, 18
Persiaran Barat, 46 050
Petaling Jaya, Selangor,
Malaysia.