

SEBIFIN®

Terbinafine Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SEBIFIN.

It does not contain all the available information about SEBIFIN.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SEBIFIN against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What SEBIFIN is used for

SEBIFIN contains terbinafine (as hydrochloride).

SEBIFIN is used to treat:

- fungal infections of the finger nails and toe nails
- tinea (ringworm) infections of the groin and body
- tinea infections of the feet, commonly called "athlete's foot"

These infections are caused by a group of fungi called dermatophytes.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

SEBIFIN terbinafine tablets are only available with a doctor's prescription. This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

How does SEBIFIN work

Terbinafine works by killing the dermatophytes.

Before you take SEBIFIN

When you must not take it

Do not take SEBIFIN if you have ever had an allergic reaction to terbinafine, the active ingredient, or to any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

If you have ever had a problem with your liver, do not take SEBIFIN until you have discussed this problem with your doctor.

This medicine is not recommended if you currently have a liver problem because it may make the problem worse.

If you had a liver problem in the past but your liver is functioning normally now, your doctor may prescribe SEBIFIN but may want to check your liver function before and during treatment with this medicine.

Do not take SEBIFIN after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take it

Tell your doctor if you are pregnant or intend to become pregnant.

There is no experience with use of SEBIFIN during pregnancy. If your doctor thinks it is necessary for you to take it, he/she will discuss with you the benefits and risks involved.

Tell your doctor if you are breast-feeding.

Breast-feeding is not recommended since terbinafine, the active ingredient in SEBIFIN, passes into breast milk. There is a possibility that your baby could be affected.

Tell your doctor if you have any problems with your kidneys.

Your doctor may want to take special precautions while you are taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and terbinafine may interfere with each other. These include:

- some medicines used to treat depression and other mental disorders, including obsessive compulsive disorders and panic attacks
- some medicines for Parkinson's disease
- beta-blocker medicines used to treat heart problems, high blood pressure and migraines, anti-arrhythmic medicines used to treat fast or irregular heart beats
- cimetidine, a medicine for stomach ulcers
- rifampicin, an antibiotic
- oral contraceptives (birth control pills). You may have problems, such as bleeding between periods, while you are taking terbinafine
- warfarin, an anticoagulant
- cyclosporine, a medicine used to help prevent organ transplant rejection or to treat certain problems with the immune system.

You may need to take different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or to avoid while taking SEBIFIN.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How SEBIFIN is given

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

The usual dose of SEBIFIN is one tablet (250 mg) each day. If you have kidney problems, the dose may be reduced to one-half of a tablet each day.

If you suffer from any kidney problem, your dose will be lower than other adults and it will be decided by your doctor.

How to take it

Take the tablet with a full glass of water. If you find that SEBIFIN upsets your stomach, try taking it immediately after a light meal.

Take the tablet at about the same time each day.

Taking your tablet at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

The length of your treatment will depend on the type of infection you have, what part of the body is affected and how well you respond to treatment.

Fungal skin infections (tinea)

If you have a tinea infection of the feet (athlete's foot), you will usually take the tablets for 2 to 6 weeks.

If you have a tinea infection of the body or groin, you will usually take the tablets for 2 to 4 weeks.

The signs and symptoms of infection may last for several weeks after the fungi (dermatophytes) have been killed.

Fungal nail infections

Fungal nail infections usually take longer to heal than fungal skin infections. You will usually take the tablets for anywhere from 6 weeks to 3 months. But if you have a nail infection of the big toe or your nails grow very slowly, you may need to take the tablets for up to 6 months.

It may take several months after you stop taking SEBIFIN for your nail to look completely normal. That is because the deformed part of the nail has to grow out and be replaced by a healthy nail.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you forget to take it

If it is almost time for your next dose (within 4 hours), skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much SEBIFIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Please keep these phone numbers handy.

Symptoms of an overdose may include headache, nausea (feeling sick), stomach pain and dizziness.

While you are using SEBIFIN

Things you must do

Make sure to take your tablet every day and continue taking it until your doctor tells you to stop.

This will ensure that all of the infection is gone and will lessen the chance of the infection coming back once you stop taking this medicine.

Make sure to have any blood tests done that are ordered by your doctor.

Any side effects on your liver, kidneys or blood can be detected by blood tests.

Tell your doctor immediately if you notice any of the following: Fever, sore throat, mouth ulcers, "flu-like" symptoms (chills, aching joints, swollen glands, lack of energy) or any other signs of infection, apart from the fungal infection you are being treated for.

If you become pregnant while taking SEBIFIN, tell your doctor immediately.

Your doctor can discuss with you the risks and benefits of taking it during pregnancy.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SEBIFIN.

Tell any other doctor, dentist or pharmacist who treats you that you are taking SEBIFIN.

Things you must not do

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking SEBIFIN until you know how it affects you.

This medicine can cause tiredness, sleepiness, dizziness or light-headedness in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Be careful to keep the infected areas dry and cool and change clothing that is in direct contact with the infected areas every day.

This will help to clear up the infection and make sure that it does not return.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SEBIFIN, even if you do not think it is connected with the medicine.

All medicines can have side effects.

Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- signs of allergy such as swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing; redness, itching or rash on the skin

- signs of a possible serious liver problem such as persistent nausea, loss of appetite, unusual tiredness, vomiting, pain in the upper right abdomen, yellowing of the skin and/or eyes, dark urine or pale bowel motions
- signs of a serious skin reaction such as painful red areas, large blisters, peeling of layers of skin, bleeding in the lips, eyes, mouth, nose or genitals. These signs may be accompanied by fever and chills, aching muscles and feeling generally unwell
- signs of a possible blood problem such as constant "flu-like" symptoms (fever, sore throat, mouth ulcers, chills, swollen glands, lack of energy) or unusual bleeding or bruising
- chest pain

The above are serious side effects that need medical attention. Serious side effects are rare.

Tell your doctor if you notice any of the following and they worry you:

- nausea (feeling sick) or vomiting
- upset stomach (heartburn, cramps, wind, belching)
- loss of appetite
- diarrhoea
- aching joints or muscles
- headache
- dizziness or light-headedness
- tiredness, sleepiness
- loss of or change in sense of taste, which usually returns to normal within several weeks of stopping SEBIFIN
- psoriasis (thickened patches of red skin, often with silvery scales)[very rare]
- hair loss (very rare)

Tell your doctor if you notice anything else that is making you unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

After using it

Storage

- Keep your medicine in the original container until it is time to take it.
- Store it in a cool, dry place below 25°C and protected from light.
- Do not store SEBIFIN or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Keep the medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Sebifin 250 mg tablets are available in packs of 14, 28 and 42 tablets.

Sebifin 250 mg tablets are white to off-white, capsule-shaped, biconvex tablets debossed with 'T' and '250' on either side of the breakline on one side and a deep breakline on the other side.

Ingredients

Active ingredient

Terbinafine hydrochloride

Inactive ingredients

- Microcrystalline cellulose,
- sodium starch glycolate,
- hypromellose,
- colloidal anhydrous silica,
- magnesium stearate and
- talc

Australian Registration No.

Sebifin 250 mg tablets - AUST R 149996

Sponsor

Ranbaxy Australia Pty Ltd.

Suite 4.02, Level 4, Building D

12 - 24 Talavera Road

North Ryde, NSW 2113

Australia

This leaflet was prepared in March 2009.

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