

Tamsil 250 mg Tablets

Terbinafine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TAMSIL 250 mg tablets. It does not contain information about other forms of terbinafine that are available without a prescription from your pharmacy.

It does not contain all the available information about TAMSIL. 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 this medicine against the benefits they expect it will provide.

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

Keep this leaflet with the medicine.

You may need to read it again.

What TAMSIL is used for

TAMSIL 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.

Terbinafine hydrochloride, the active ingredient in TAMSIL, works by killing the 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.

TAMSIL is 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.

Before you take it

When you must not take it

Do not take TAMSIL 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.

Do not take TAMSIL if you:

- have any problems with your kidneys
- have or ever had a problem with your liver

Do not take TAMSIL until you have discussed these problems 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 TAMSIL but may want to check your liver function before and during treatment with the medicine.

Do not take TAMSIL 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 TAMSIL 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 breastfeeding.

Breastfeeding is not recommended since terbinafine, passes into the breast milk. There is a possibility that your baby could be affected.

Taking other medicines

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

Some medicines and TAMSIL 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
- some medicines used to treat an irregular heartbeat, heart problems, high blood pressure and migraines (e.g. metaproterenol)
- some medicines used to treat stomach ulcers (e.g. cimetidine)
- some antibiotics (e.g. rifampicin)
- caffeine
- cyclosporin, a medicine used to help prevent organ transplant rejection or treat certain problems with the immune system
- oral contraceptives (birth control pills). You may have problems, such as bleeding between periods, while you are taking TAMSIL
- warfarin, a medicine used to prevent blood clots.

You may need to take different amounts of your medicine or you may need to take different medicines. Your doctor and pharmacist have more information.

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

How to take it

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 TAMSIL is one tablet (250 mg) each day taken orally. If you have kidney problems, the dose may be reduced to one-half a tablet each day.

How to take it

Take the tablet with a full glass of water. If you find that this medicine 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 to 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 TAMSIL 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 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.

Ask your pharmacist for some hints if you have trouble remembering when to take your medicine.

If you take too much (Overdose)

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

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

While you are taking TAMSIL

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 fungal infection you are being treated for.

If you become pregnant while taking TAMSIL, tell your doctor immediately.
Your doctor can discuss with you the risks and benefits of taking it during pregnancy.

Remind your doctor and pharmacist that you are taking TAMSIL if you are about to be started on any new medicine.

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

Things you must not do

Do not give this medication 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 TAMSIL 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 the clothing that is in direct contact with the infected area 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 TAMSIL, 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 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
- Light-headedness
- Tiredness, sleepiness
- Loss of or change in sense of taste, which usually returns to normal within several weeks of stopping Tamsil 250 mg
- Psoriasis (thickened patches of red skin, often with silvery scales) [very rare]
- Hair loss (very rare)
- Tingling or numbness (very rare)
- Decreased physical sensitivity (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.

Sponsor

TAMSIL is supplied in Australia by:

Aspen Pharma Pty Ltd

34-36 Chandos Street

St Leonards NSW 2065

Australia

Tamsil 250 mg Tablets: AUST R 167577

This leaflet was last revised in April 2012.

After using it

Storage

- Keep your medicines 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 TAMSIL 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 meters 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

White to off white round tablet embossed "R250" on one side and score (bisect) line on the other side; pack of 42.

Ingredients

The active ingredient in TAMSIL is terbinafine (as hydrochloride). Each tablet contains 250 mg of terbinafine.

Tamsil tablets also contain:

- Microcrystalline cellulose
- Colloidal anhydrous Silica
- Hypromellose
- Magnesium stearate
- Croscarmellose sodium

If you are concerned about which tablet you are taking or any of the above ingredients, talk to your doctor or pharmacist before starting to take TAMSIL.