

Lamifen™ Tablets 250 mg

terbinafine

What you need to know about Lamifen™ Tablets

Your doctor has decided that you need this medicine to help treat your condition.

Please read this leaflet carefully before you start to take your medicine. It contains important information.

Keep the leaflet in a safe place because you may want to read it again.

If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours.

If any side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Lamifen™ Tablets are and what they are used for

Terbinafine, the active ingredient in Lamifen™ Tablets, is an antifungal medicine. Lamifen™ Tablets are used to treat a number of fungal infections of the skin and nails.

2. Things to consider before you start to take Lamifen™ Tablets

Some people MUST NOT take Lamifen™ Tablets. Talk to your doctor if:

- you think you may be allergic to terbinafine or to any of the other ingredients of Lamifen™ Tablets. (These are listed in Section 6.)
- you are breast-feeding

You should also ask yourself these questions before taking Lamifen™ Tablets. If the answer to any of these questions is YES, tell your doctor or pharmacist because Lamifen™ 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?

Children should not normally be given Lamifen™ Tablets except in necessary.

Are you 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.*

Will there be any problems with driving or using machinery?

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

3. How to take Lamifen™ Tablets

The doctor will decide what dose of Lamifen™ Tablets you should take. Always take the tablets exactly as your doctor has told you to. The dose will be on the pharmacist's label. Check the label carefully. It should tell you how many tablets to take, and how often. If you are not sure, ask your doctor or pharmacist. Keep taking the tablets for as long as you have been told unless you have any problems. In that case, check with your doctor.

The usual dose for adults, including the elderly, is 250 mg 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 may need to be treated for **6 months or longer**.
- If your kidneys are not working very well, your doctor may reduce the dose of Lamifen™ Tablets you take.
- Swallow the tablets whole with a glass of water.

For children:

No data are available in children under two years (usually < 12 kg)
Children weighing <20 kg. 62.5 (1/4 tablet) once daily.
Children weighing 20 to 40 kg. 125mg (1/2 tablet) once daily .
Children weighing > 40 kg. 250 mg (one tablet) once daily.

What if you forget to take a dose?

If you miss taking a Lamifen™ 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.

What if you take too many tablets?

All tablets can be risky if you take too many. If you take too many Lamifen™ 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.

4. Possible side effects

Lamifen™ 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).
- 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
- 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 when 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
 - Vertigo
 - 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: Psoriasis like skin eruptions, or worsening of psoriasis, severe skin reactions including a rash or eruption of small pus containing blisters. 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).

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.

5. How to store Lamifen™ Tablets

Store the tablets in their original pack away from direct light. Do not store above 30 °C. Do not take the tablets after their expiry date which is printed on the outside of the pack. If your doctor tells you to stop taking Lamifen™ Tablets, please take any unused tablets back to your pharmacist to be destroyed. Only keep the tablets if the doctor tells you to. Do not throw them away with your normal household water or waste. This will help to protect the environment.

6. Further information

Lamifen™ Tablets are round, white to off white tablets, plain on one side and on the other side breaking line with engrave 'JP 24'.

And they contain 250 mg of the active ingredient terbinafine. They also contain the inactive ingredients: microcrystalline cellulose, maize starch, sodium starch glycolate, hydroxy propyl methylcellulose, colloidal silicone dioxide, magnesium stearate.

They come in blister packs of 7 or 14 tablets.

Not all pack sizes are may be marketed.

Marketing Authorisation Holder and Manufacturer

Jamjoom Pharmaceuticals Co., Jeddah, Saudi Arabia.

Tel: +966-12-6081111, Fax: +966-12-6081222.

Website: www.jamjoompharma.com

To report any side effect(s):

• Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)
 - o Fax: +966-11-205-7662
 - o Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
 - o Toll free phone: 8002490000
 - o E-mail: npc.drug@sfd.gov.sa
 - o Website: www.sfd.gov.sa/npc

• Other GCC States:

- Please contact the relevant competent authority.

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THIS IS A MEDICAMENT

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of the reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists



Lamifen™ is a quality product manufactured by:



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