

Package leaflet: Information for the user

Lamisil AT Cream Terbinafine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine is available without prescription. However, you still need to use Lamisil AT Cream carefully to get the best results from it.

- Please keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Lamisil AT Cream is and what it is used for
2. What you need to know before you use Lamisil AT Cream
3. How to use Lamisil AT Cream
4. Possible side effects
5. How to store Lamisil AT Cream
6. Contents of the pack and other information

1. What Lamisil AT Cream is and what it is used for

Lamisil AT Cream contains the active ingredient terbinafine hydrochloride which is an antifungal used to treat fungal skin infection such as:

- **Athlete's foot (tinea pedis)**

Athlete's foot appears only on the feet (usually both, but not always), usually in between the toes. It can also appear on the instep, soles, or other areas of the feet. The most common type of athlete's foot causes cracking or scaling of the skin, but you may also have mild swelling, blisters, or weeping ulcers.

Lamisil AT Cream is recommended for athlete's foot when it occurs between the toes. If you have a fungal nail infection (fungus inside and under the nail) with discolouration of the nails and changes in nail texture (thick or flaky), you should consult your doctor because Lamisil AT Cream is not appropriate for this type of infection.

- **Dhobie itch/jock itch (tinea cruris)**

Dhobie itch appears in the groin and inner thigh area, usually on both sides but often with one side more than the other, where it can spread further between the legs to the buttocks, or up towards the stomach. Dhobie itch looks like a clearly bordered rash, which may have blisters.

2. What you need to know before you use Lamisil AT Cream

Do NOT use Lamisil AT Cream if you:

- are allergic (hypersensitive) to any of the ingredients in the product (see Section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Lamisil AT Cream. The cream is for external use only. Do not use on the face. Avoid contact with eyes. In case of accidental contact with the eyes, rinse thoroughly with running water.

Other medicines and Lamisil AT Cream

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription.

Pregnancy and breast-feeding

Do not use the cream if you are pregnant or breast-feeding, unless advised to by your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Lamisil AT Cream is not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Lamisil AT Cream

The cream contains some ingredients which you may need to be aware of:

- This medicine contains 75 mg **benzyl alcohol** in each tube which is equivalent to 10 mg/g. **Benzy alcohol** may cause mild local irritation.
- **cetyl alcohol** and **stearyl alcohol**: may cause local skin reactions (e.g. contact dermatitis). For other ingredients see Section 6.

3. How to use Lamisil AT Cream

Always use Lamisil AT Cream exactly as your doctor or pharmacist has told you; you should check with him/her if you are not sure.

This medicine is for external use only.

Usual dose for adults

Athlete's Foot: apply the cream once a day for one week.

Dhobie Itch: apply the cream once a day for one week.

Directions for use:

- Cleanse and dry the affected areas thoroughly and wash your hands. Treatment can be helped by keeping the affected areas clean by regular washing and careful drying with your own clean towels and clothes, and not rubbing or scratching the skin.
- Unscrew the tube. If it is still sealed, remove the protective foil or pierce it using the point in the cap.
- Then gently squeeze out a small amount of the cream onto your finger.
- Apply just enough cream to form a thin layer on the affected skin and surrounding areas.
- Rub in gently. When used between the toes, buttocks or on the groin, the treated area may be covered with a light, fresh gauze strip, especially at night.
- Replace the cap on the tube and wash your hands. If you have not noticed any signs of improvement within 2 weeks of first starting treatment, please seek advice from your doctor or pharmacist.

Children

The cream is NOT recommended for use on children under 16 years of age.

If you use more Lamisil AT Cream than you should

Contact your doctor or nearest hospital emergency department if you, or someone else, has swallowed some cream. Take any remaining medicine and this leaflet with you if possible.

If you forget to use Lamisil AT Cream

If you miss an application, apply the cream as soon as possible then continue your treatment as before. If you only remember at the time of your next application, just apply the cream and carry on as normal. It is important to try to use the cream at the correct times as forgotten applications could carry a risk of the infection recurring.

If you stop using Lamisil AT Cream

Infections may come back if you do not use the cream regularly, or if you stop the treatment too early. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Lamisil AT Cream can cause side effects, although not everybody gets them.

STOP using the cream and seek medical help immediately if you have any of the following very rare **allergic reactions**:

- difficulty breathing or swallowing, swelling of the mouth, face, lips, tongue or throat (severe allergic reaction).
- severe itching of the skin, with a red rash or raised lumps, hives or blisters.

Lamisil AT Cream can occasionally cause redness, stinging, peeling, itching, pain, irritation or scabbing at the application site. These effects are usually harmless and you can carry on using the cream.

Some side effects are common: (may affect up to 1 in 10 people): skin peeling, itching.

Some side effects are uncommon: (may affect up to 1 in every 100 people): skin lesions, scab, skin colour changes, redness, burning, pain and irritation at the site of application.

Some side effects are rare: (may affect up to 1 in a 1000 people): eye irritation, dry skin, contact dermatitis, eczema, worsening of symptoms.

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 HPRC Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lamisil AT Cream

Keep out of the sight and reach of children.

Do not store above 30°C.

Do not use this medicine after the expiry (EXP) date shown on the box and tube. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Lamisil AT Cream contains

The **active** ingredient is terbinafine hydrochloride 1.0% w/w.

The **other** ingredients are sodium hydroxide, benzyl alcohol, sorbitan stearate, cetyl palmitate, cetyl alcohol, stearyl alcohol, polysorbate 60, isopropyl myristate, purified water. (See also end of Section 2 for further information on some of the ingredients).

What Lamisil AT Cream looks like and contents of the pack

Lamisil AT Cream is a white, smooth, glossy cream. Lamisil AT Cream is available in packs of 7g, 7.5g, 10g or 15g cream. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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