

LAMISIL CREAM 1%®

Terbinafine hydrochloride (1%w/w)

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What Lamisil Cream is used for

Lamisil Cream is used to treat the topical fungal infections below:

- athlete's foot (tinea pedis) – especially when it occurs between the toes
- dhobie (jock) itch (tinea cruris) – itchy rash with a clear border which often occurs on the groin and inner thigh area.
- ringworm (tinea corporis) – circular patches of red rash which may appear scaly
- skin candidiasis (intertrigo or
- sweat rash) – redness, itching and scaling in folded areas of skin which are wet with perspiration.
- pityriasis (tinea) versicolor – scaly patches that become white areas due to loss of skin pigmentation.

How Lamisil Cream works

Lamisil Cream is an antifungal, and works by killing the fungi causing your skin problem.

Before you use Lamisil Cream

When you must not use it

- Do NOT use in children under 12 years of age.
- Do NOT use to treat fungal nail infection (inside and under the nail), with discoloration of the nails and change in nail texture (thick, flaky). Please see your doctor for appropriate treatment for this type of infection
- Do NOT use Lamisil Cream:
 - If you are allergic (hypersensitive) to terbinafine hydrochloride or any of the other ingredients of this medicine (listed in Product Description).

Important information about some of the ingredients of Lamisil Cream

Lamisil Cream contains

- cetyl alcohol and stearyl alcohol: may cause local skin reactions (e.g. contact dermatitis).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Should not be used during pregnancy unless clearly necessary.

Do not use Lamisil Cream while breast-feeding. Do not allow infants to come into contact with any treated areas, including the breasts. The ingredients can pass into your breast milk.

Before you start to use it

Talk to your doctor or pharmacist before using Lamisil Cream.

- It is for external use only.
- Do not use it in the mouth or swallow it.
- Keep the cream away from your eyes. If the cream accidentally gets into your eyes, rinse the eye thoroughly with running water. See your doctor if you are still in any discomfort.

Taking other medicines

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Do not apply other medicinal products on the areas being treated.

How to use Lamisil Cream

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

It is important to use Lamisil Cream correctly. Follow the instructions carefully.

Directions for use:

Adults and adolescents aged 12 years and over:

- Clean and dry the affected skin and surrounding areas, and wash your hands.

- Unscrew the cap, and if using for the first time, use the point in the cap to pierce the top of the tube, then gently squeeze the tube.
- Apply enough cream to put a thin layer on the affected skin and surrounding areas.
- Rub in gently.
- Replace the cap on the tube.
- Wash your hands after touching the infected skin so that you do not spread the infection on yourself or to others.

If you are treating an infection in folded areas of your body you can cover the treated area with a gauze strip, especially at night. If you do, use a fresh, clean gauze strip each time you apply the cream.

If applied to face, keep away from your eyes.

How much to use

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

When to use Lamisil Cream

- **Athlete's foot:** apply once a day.
- **Dhobie (jock) itch and ringworm:** apply once a day.
- **Skin candidiasis (intertrigo or sweat rash):** apply once or twice a day.
- **Pityriasis versicolor:** apply once or twice a day.

How long to use Lamisil Cream

Apply Lamisil Cream to the infected areas as follows:

- **Athlete's foot:** apply for one week.
- **Dhobie (jock) itch and ringworm:** apply for one week.
- **Skin candidiasis (intertrigo or sweat rash):** apply for one to two weeks. This may look like ringworm or dhobie itch but it occurs in elderly or obese patients with moist areas of overlapping folds of skin, or those with other conditions such as diabetes. The longer treatment duration (2 weeks) may be needed to

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treat candidiasis.

- **Pityriasis versicolor:** apply for two weeks.

Use the cream for the recommended treatment period even if the infection seems to be better after a few days. Infections usually appear to improve within a few days, but may reappear if the cream is not applied regularly or is stopped too early.

Lamisil Cream should start to improve your skin condition in a few days. Lamisil Cream will continue to work even after you have completed the treatment.

If you have not noticed any signs of improvement within 2 weeks of first starting treatment, please see your doctor or pharmacist who will advise you.

To help with the treatment

To help with the treatment keep the affected area clean by washing it regularly. Dry it carefully without rubbing, but dabbing it gently. Try not to scratch the area although it may be itchy, because this could cause further damage and slow the healing process or spread the infection.

Because these infections can be passed on to other people, remember to keep your own towel and clothes and do not share them with others. To protect yourself from re-infection, these should be washed frequently.

If you forget to use Lamisil Cream

If you forget an application of the cream, apply it as soon as possible and then carry on as normal. If you only remember at the time of the next application, just apply the usual amount and then carry on as normal. Do not apply a double dose to make up for a forgotten dose.

Try to use the cream as indicated. This is important to get the best results and prevent the infection from returning.

If you use too much of Lamisil Cream (overdose)

Symptoms/signs of overdose following ingestion of terbinafine may include headache, nausea,

epigastric pain and dizziness.

If you or someone else accidentally swallows some Lamisil Cream, please tell your doctor who will advise you on what to do.

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Things you must not do

- It is for external use only.
- Do not use it in the mouth or swallow it.
- Avoid contact of the cream with your eyes. If the cream accidentally gets into your eyes, rinse thoroughly with running water. If any discomfort persists, see your doctor.

Things to be careful of

Driving and using machines

Lamisil Cream has no influence on the ability to drive and use machines.

Side effects

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

Most people benefit from using Lamisil Cream.

STOP using Lamisil Cream and seek medical help immediately if you have any of the following which may be signs of an allergic reaction:

- difficulty in breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

The following side effects have been reported:

Skin problems such as skin peeling, itching, skin lesion, scab, skin disorder, skin colour changes, redness, burning, pain, application site pain, application site irritation.

Other side effects include:

Dry skin, eczema, contact dermatitis which is a type of inflammation of the skin, skin rash, worsening of disease symptoms, allergic reactions.

Be aware that in rare cases the underlying fungal infection may be aggravated.

If Lamisil Cream is accidentally applied to the eyes, eye irritation may occur.

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 [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Lamisil Cream

Storage

- Keep this medicine out of the reach and sight of children.
- Do not store above 30°C.
- Do not use Lamisil Cream after the expiry date which is stated on the package. The expiry date refers to the last day of that month.
- Keep the tube closed and in the carton.
- Store in the original package.

Disposal

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

Product Description

What it looks like

The cream is white, smooth, glossy cream in a varnished aluminium tube.

Ingredients

- Active ingredients

Terbinafine hydrochloride.

- Inactive ingredients

Purified water, sodium hydroxide, benzoyl alcohol, sorbitan stearate, cetyl palmitate, cetyl alcohol, stearyl alcohol, polysorbate 60, isopropyl myristate.

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MAL Number

MAL05092235XR

Manufacturer

Haleon CH SARL, Nyon, Switzerland.

Product Registration Holder

Zuellig Pharma Sdn. Bhd.

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