

Lamisil

Spray 1%

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

Always use this medicine exactly as described in this leaflet, or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects listed or not listed in this leaflet.
- You must talk to a doctor, if you do not feel better, or if you feel worse.

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2. What Lamisil Spray is and what it is used for
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1. What is contained in Lamisil Spray

The active substance is Terbinafine hydrochloride (1 g contains 10 mg Terbinafine hydrochloride equivalent to 8.8 mg/g Terbinafine base)

The other ingredients are Purified water, Ethanol 96%, Propylene glycol, Macrogol cetostearyl ether/polyoxyl 20 cetostearyl ether.

2. What Lamisil Spray is and what it is used for

Lamisil Spray is intended for treatment of fungal infections of the skin:

- Athlete's foot (Tinea pedis)

3. What you need to know before you use Lamisil Spray

a. Do not use Lamisil Spray in cases of hypersensitivity to Terbinafine hydrochloride or any other ingredient in Lamisil Spray.

b. Warnings and precautions:

- Lamisil Spray is intended for external use only.
- Avoid contact with the eyes. Lamisil Spray may irritate the eyes and should therefore not be used in the face.
- When accidentally applied to the eye, immediately and thoroughly flush the eye with running water. Consult your doctor, if the complaints do not disappear.
- Lamisil Spray should be used with caution with skin lesions, since the alcohol or propylene glycol may cause irritations.
- Lamisil Spray should not be used in women who are breastfeeding. Infants must not come into contact with treated skin areas.
- Do not swallow or use in the mouth.
- Do not breathe in the spray. If any discomfort persists, see your doctor.
- Keep out of sight and reach of children.

c. Pregnancy and breastfeeding

Pregnancy

- There are no controlled studies on pregnant women. Reproduction studies in animals have shown no risks to the foetus.
- Do not use Lamisil Spray during pregnancy, unless it is clearly required.

Breastfeeding

- Terbinafine hydrochloride is excreted into the breast milk, even though only in small amounts.
- It is not known whether this small amount in the breast milk may have negative effects on the child.
- Lamisil Spray should not be used in women who are breastfeeding.
- Infants must not come into contact with treated skin areas.

d. Driving and using machines

- Cutaneous application of Terbinafine hydrochloride has no influence on the ability to drive and use machines.

4. How to use Lamisil Spray

For use on the skin:

Cleanse and dry the affected areas thoroughly before application of Lamisil Spray.

Adults:

- Apply Lamisil Spray once per day.
- When using Lamisil Spray, adequately moisten the affected skin and surrounding areas.

Duration and frequency of treatment:

- Athlete's foot: Once a day for one week
- Relief of clinical symptoms usually occurs within a few days.
- Irregular use or premature discontinuation of treatment carries the risk of recurrence.
- If there are no signs of improvement after one week, the diagnosis should be verified.

Children:

- Not recommended for use in children below 12 years of age, due to insufficient data on safety and efficacy.
- The safety and efficacy in children and adolescents less than 18 years of age have not been established.
- Due to limited clinical data, application of Lamisil Spray in children and adolescents less than 18 years of age is not recommended.

Elderly patients:

- There are no indications that elderly patients require a different dosage or experience side-effects different to those of younger patients.

5. Possible side effects

Like all medicines, Lamisil Spray can cause side effects, although not everybody gets them. Most people benefit from using Lamisil Spray. Statements are defined as follows: Very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$, $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$).

STOP using Lamisil Spray 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

Some side effects are common (may affect up to 1 in every 10 people): Skin peeling, Itching, Skin exfoliation, Pruritis.

Some side effects are uncommon (may affect up to 1 in every 100 people): Skin lesion, Scab, Skin disorder, Skin color changes, Redness, Burning, Pain, Application site pain, Application site irritation.

Some side effects are rare (may affect up to 1 in every 1,000 people): Dry skin, Eczema, Contact dermatitis, Condition aggravated.

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

Side effects with unknown frequency: Hypersensitivity, Rash.

If any other side effects that are not described in this leaflet occur, you should immediately stop the treatment with Lamisil Spray and inform your doctor or your pharmacist.

Interaction: No drug interactions are known with the topical forms of Terbinafine hydrochloride.

6. Overdose

Due to the low systemic absorption of locally applied Terbinafine, an overdose is very unlikely.

Accidental ingestion of the contents of one bottle of Lamisil Spray 30 ml, containing 300 mg Terbinafine hydrochloride, is comparable to taking one tablet of Lamisil 250 mg (corresponding to an oral standard dosage for adults).

If a larger amount of a topical Lamisil Spray formulation is accidentally ingested, the expected side effects are similar to those after taking an overdose of Lamisil tablets:

These include headache, nausea, upper abdominal pain and dizziness.

Note the alcohol content of 28.87% (v/v), if accidental oral ingestion of Lamisil Spray occurs.

Treatment in case of overdose:

If accidentally ingested, the recommended treatment of overdosage consists of eliminating the medicinal product by the administration of activated charcoal, and giving symptomatic supportive therapy, if needed.

Talk to your doctor or pharmacist immediately, if you accidentally swallow this medicine.

7. How to store Lamisil spray

- Keep this medicine out of sight and reach of children.
- Do not store above 30°C.
- Do not use this medicine after the expiry date which is stated on the pack.
- The expiry date refers to the last day of that month.
- Store in the original package.
- Contains ethanol: Keep away from flames.

8. Contents of the pack and other information

Available in 30 ml and 15 ml.

Manufacturer and Marketing Authorisation Holder:

Manufactured by:

Delpharm Huingue S.A.S, Huinge/France

For: GSK Consumer Healthcare Schweiz AG, Switzerland

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THIS IS A MEDICAMENT

- a. Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- b. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- c. The doctor and the pharmacist are the experts in medicines, their benefits and their risks.
- d. Do not by yourself interrupt the period of treatment prescribed.
- e. Do not repeat the same prescription without consulting your doctor.
- f. Keep medicament out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists

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