

LAMIRASE

Cream & Solution

Composition

Lamirase Cream

Terbinafine HCL 1%

Lamirase Solution

Each 1 ml contains Terbinafine HCL 10 mg

Action

Cream & Solution

Terbinafine HCl is a synthetic allylamine derivative. Terbinafine HCl exerts its antifungal effect by inhibiting squalene epoxidase, a key enzyme in sterol biosynthesis in fungi. This action results in a deficiency in ergosterol and a corresponding accumulation of squalene within the fungal cell and causes fungal cell death.

Terbinafine has been shown to be active against most strains of the following organisms both in vitro and in clinical infections at indicated body sites:

Epidermophyton floccosum , *Trichophyton mentagrophytes*, *Trichophyton rubrum*

Indications

Cream

Lamirase cream is indicated for the topical treatment of the following dermatologic infections: Interdigital tinea pedis (athlete's foot), tinea cruris (jock itch), or tinea corporis (ringworm) due to *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, or *Trichophyton rubrum*.

Solution

Prescription Lamirase solution 1% is indicated for the topical treatment of tinea (pityriasis) versicolor due to *Malassezia furfur* (formerly *Pityrosporum ovale*).

Contraindications

Contraindicated in individuals who have known or suspected hypersensitivity to Terbinafine or any other of its components.

Warnings

Terbinafine HCl is not for ophthalmic, oral, or intravaginal use.

Adverse Reactions

Cream

Patients treated with Terbinafine HCl discontinued therapy due to adverse events and these reactions included irritation (1%), burning (0.8%), itching (0.2%), and dryness (0.2%).

Solution

Patients treated with Terbinafine HCl discontinued therapy due to adverse events and these reactions included (burning or irritation) (1.3%), itching (1.1%), skin exfoliation (1.0%) and erythematous rash (0.9%)

Precautions

General

If irritation or sensitivity develops with the use of Terbinafine HCl, treatment should be discontinued and appropriate therapy instituted. Terbinafine HCl solution, 1%, may be irritating to the eyes.

Information for the patient

Cream

- Use Lamirase cream as directed by the physician and avoid contact with the eyes, nose, mouth, or other mucous membranes.
- Use the medication for the treatment time recommended by the physician.
- Inform the physician if the area of application shows signs of increased irritation or possible sensitization (redness, itching, burning, blistering, swelling, or oozing).
- Avoid the use of occlusive dressings unless otherwise directed by the physician.

Solution

- Use Lamirase solution 1%, as directed by the physician and avoid contact with the eyes, nose, mouth, or other mucous membranes. The spray form should not be used on the face. In case of accidental contact with the eyes, rinse eyes thoroughly with running water and consult a physician if any symptoms persist.
- Apply Lamirase solution 1%, twice daily.
- Cleanse and dry the affected areas thoroughly before applying Lamirase solution. Sufficient solution should be applied to wet the treatment area(s) thoroughly, and to cover the affected skin and surrounding area.
- Use the medication for the full treatment time (1 week) even though symptoms may have improved.
- Inform the physician if the area of application shows signs of increased irritation or possible sensitization (redness, itching, burning, blistering, swelling, or oozing).
- Notify the physician if there is no improvement after 1 week of treatment.
- Avoid the use of occlusive dressings unless otherwise directed by the physician.

Pregnancy

Category B

Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

Nursing mothers

Because of the small amount of data on human neonatal exposure, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Nursing mothers should avoid application of Terbinafine HCl to the breast.

Pediatric use

The safety and efficacy of Terbinafine HCl have not been established in pediatric patients.

Drug Interactions

Potential interactions between Terbinafine HCl cream and solution with other drugs have not been systematically evaluated.

Dosage and Administration

Cream

In the treatment of interdigital tinea pedis (athlete's foot), Lamirase cream should be applied to cover the affected and immediately surrounding areas twice daily until **clinical signs and symptoms are significantly improved**. In many patients, this occurs by Day 7 of drug therapy. The duration of drug therapy should be for a minimum of 1 week and should not exceed 4 weeks.

In the treatment of tinea cruris (jock itch) or tinea corporis (ringworm), Lamirase cream should be applied to cover the affected and immediately surrounding areas once or twice daily **until clinical signs and symptoms are significantly improved**. In many patients, this occurs by Day 7 of drug therapy. The duration of drug therapy should be for a minimum of 1 week and should not exceed 4 weeks.

Note: Many patients treated with shorter durations of therapy (1-2 weeks) continue to improve during the 2-4 weeks after drug therapy has been completed. As a consequence, patients should not

be considered therapeutic failures until they have been observed for a period of 2-4 weeks off therapy.

If successful outcome is not achieved during the post-treatment observation period, the diagnosis should be reviewed.

Solution

Lamirase solution 1%, is applied twice daily for 1 week. The affected areas should be cleansed and dried thoroughly before applying Lamirase solution 1%. Sufficient solution should be applied to wet the treatment area(s) thoroughly, and to cover the affected skin and surrounding area. If successful outcome is not achieved during the post treatment period, the diagnosis should be reviewed.

Presentation

Solution

Lamirase 1 % solution is supplied in a 30 ml pump spray bottle with a spray-pump assembly, which will also function upside-down, and protective cap.

Cream

Tube of 15 g