
LOTRISONE[®]

Cream

LOTRISONE[®]

Lotion

(clotrimazole and betamethasone dipropionate)

Patient's Instructions for Use

SHAKE LOTION WELL BEFORE EACH USE

Patient Information Leaflet

What is LOTRISONE[®] Cream or Lotion?

LOTRISONE Cream and Lotion are medications used on the skin to treat fungal infections of the feet, groin and body, as diagnosed by your doctor. LOTRISONE Cream or Lotion should be used for fungal infections that are inflamed and have symptoms of redness and/or itching. Talk to your doctor if your fungal infection does not have these symptoms. LOTRISONE Cream and Lotion contain a corticosteroid. Notify your doctor if you notice side effects with the use of LOTRISONE Cream or Lotion (see “**What are the possible side effects of LOTRISONE Cream and Lotion?**” below). LOTRISONE Cream or Lotion is not to be used in the eyes, in the mouth, or in the vagina.

How do LOTRISONE[®] Cream and Lotion work?

LOTRISONE Cream and Lotion are combinations of an antifungal agent (clotrimazole) and a corticosteroid (betamethasone dipropionate). Clotrimazole works against fungus. Betamethasone dipropionate, a corticosteroid, is used to help relieve redness, swelling, itching, and other discomforts of fungal infections.

Who should NOT use LOTRISONE[®] Cream or Lotion?

LOTRISONE Cream and Lotion are not recommended for use in patients under the age of 17 years. LOTRISONE Cream or Lotion is not recommended for use in diaper rash.

Patients who are sensitive to clotrimazole and betamethasone dipropionate, other corticosteroids or imidazoles, or any ingredients in the preparation should not use LOTRISONE Cream and Lotion.

How should I use LOTRISONE[®] Cream or Lotion?

Gently massage sufficient LOTRISONE Cream or Lotion into the affected and surrounding skin areas twice a day, in the morning and evening. Treatment for 2 weeks on the groin or on the body, and for 4 weeks on the feet is recommended. The use of LOTRISONE Cream or Lotion for longer than 4 weeks is not

recommended for any condition. Prolonged use of LOTRISONE Cream or Lotion may lead to unwanted side effects.

What other important information should I know about LOTRISONE[®] Cream and Lotion?

1. This medication is to be used for the full prescribed treatment time, even though the symptoms may have improved. Notify your doctor if there is no improvement after 1 week of treatment on the groin or body or after 2 weeks on the feet.
2. This medication should only be used for the disorder for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped.
4. Other corticosteroid-containing products should not be used with LOTRISONE without first talking with your physician.
5. Any signs of side effects where LOTRISONE Cream or Lotion is applied should be reported to your doctor.
6. When using LOTRISONE Cream or Lotion in the groin area, it is especially important to use the medication for 2 weeks only, and to apply the cream or lotion sparingly. You should tell your doctor if your problem persists after 2 weeks. You should also wear loose-fitting clothing so as to avoid tightly covering the area where LOTRISONE Cream or Lotion is applied.
7. This medication is not recommended for use in diaper rash.

What are the possible side effects of LOTRISONE[®] Cream and Lotion?

The following side effects have been reported with topical corticosteroid medications: itching, irritation, dryness, infection of the hair follicles, increased hair, acne, fragile blood vessels, sensitization (local reactions upon repeated application of product), change in skin color, allergic skin reaction, skin thinning, and stretch marks. In children, reported adverse events for LOTRISONE Cream include slower growth, Cushing's syndrome (a type of hormone imbalance that can be very serious), and local skin reactions, including thinning skin and stretch marks. Hormone imbalance (adrenal suppression) was demonstrated in clinical studies in children.

Can LOTRISONE[®] Cream or Lotion be used if I am pregnant or plan to become pregnant or if I am nursing?

Before using LOTRISONE Cream or Lotion, tell your doctor if you are pregnant or plan to become pregnant. Also, tell your doctor if you are nursing.

How should LOTRISONE[®] Cream or Lotion be stored?

LOTRISONE Cream should be stored at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature].

**LOTRISONE Lotion should be stored at 25°C (77°F) in the upright position only; excursions permitted between 15°C and 30°C (59°F and 86°F).
Shake well before using LOTRISONE Lotion.**

General advice about prescription medicines

This medicine was prescribed for your particular condition. Only use LOTRISONE[®] Cream or Lotion to treat the condition for which your doctor has prescribed. Do not give LOTRISONE Cream or Lotion to other people. It may harm them.

This leaflet summarizes the most important information about LOTRISONE Cream and Lotion. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about LOTRISONE Cream and Lotion that is written for health professionals.

Rx only

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