

Patient Information
LOTRISONE® (LOW-tre-zone)
(clotrimazole and betamethasone dipropionate) cream, 1%/0.05%

Important information: LOTRISONE cream is for use on skin only. Do not use LOTRISONE cream in your eyes, mouth, or vagina.

What is LOTRISONE cream?

- LOTRISONE cream is a prescription medication used on the skin (topical) to treat fungal infections of the feet, groin, and body in people 17 years of age and older. LOTRISONE cream is used for fungal infections that are inflamed and have symptoms of redness or itching.
- LOTRISONE cream should not be used in children under 17 years of age.

Before using LOTRISONE cream, tell your healthcare provider about all your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if LOTRISONE cream will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if LOTRISONE cream passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take other corticosteroid medicines by mouth or use other products on your skin or scalp that contain corticosteroids.

How should I use LOTRISONE cream?

- Use LOTRISONE cream exactly as your healthcare provider tells you to use it.
- Use LOTRISONE cream for the prescribed treatment time, even if your symptoms get better.
- Do not use more than 45 grams of LOTRISONE cream in 1 week.
- Do not bandage, cover, or wrap the treated area unless your healthcare provider tells you to. Wear loose-fitting clothing if you use LOTRISONE cream in the groin area.
- Do not use LOTRISONE cream on your face or underarms (armpits).
- **For treatment of fungal infections of the groin and body:**
 - Apply a thin layer of LOTRISONE cream to the affected skin area 2 times a day for 1 week.
 - Tell your healthcare provider if the treated skin area does not improve after 1 week of treatment.
 - Do not use LOTRISONE cream for longer than 2 weeks.
- **For treatment of fungal infections of the feet:**
 - Apply a thin layer of LOTRISONE cream to the affected skin area 2 times a day for 2 weeks.
 - Tell your healthcare provider if the treated skin area does not improve after 2 weeks of treatment. Do not use LOTRISONE cream longer than 4 weeks.
 - Wash your hands after applying LOTRISONE cream.

What should I avoid while using LOTRISONE cream?

LOTRISONE cream should not be used to treat diaper rash or redness. You should avoid applying LOTRISONE cream in the diaper area.

What are the possible side effects of LOTRISONE cream?

LOTRISONE cream may cause serious side effects, including:

- **LOTRISONE cream can pass through your skin.** Too much LOTRISONE cream passing through your skin can cause your adrenal glands to stop working. Your healthcare provider may do blood tests to check for adrenal gland problems.
- **Vision problems.** Topical corticosteroids may increase your chance of developing cataracts and glaucoma. Tell your healthcare provider if you develop blurred vision or other vision problems during treatment with LOTRISONE cream.

The most common side effects of LOTRISONE cream include burning, tingling, rash, swelling, and infections.

These are not all the possible side effects of LOTRISONE cream.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store LOTRISONE cream?

- Store LOTRISONE cream at room temperature between 68 to 77°F (20 to 25°C).
- Keep LOTRISONE cream and all medicines out of the reach of children.

General information about the safe and effective use of LOTRISONE cream.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use LOTRISONE cream for a condition for which it was not prescribed. Do not give LOTRISONE cream to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about LOTRISONE cream that is written for health professionals.

What are the ingredients in LOTRISONE cream?

Active ingredients: clotrimazole and betamethasone dipropionate

Inactive ingredients: benzyl alcohol as a preservative, cetareth-30, cetyl alcohol plus stearyl alcohol, mineral oil,

phosphoric acid, propylene glycol, purified water, sodium phosphate monobasic monohydrate, and white petrolatum

Distributed by: Merck Sharp & Dohme Corp., a subsidiary of
 **MERCK & CO., INC.**, Whitehouse Station, NJ 08889, USA

For patent information: www.merck.com/product/patent/home.html

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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