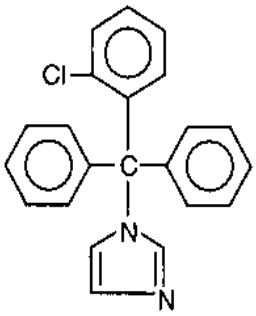
LOTRISONE® Cream, USP
LOTRISONE® Lotion
(clotrimazole, USP and betamethasone dipropionate, USP)

FOR TOPICAL USE ONLY, NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE, NOT RECOMMENDED FOR PATIENTS UNDER THE AGE OF 17 YEARS AND NOT RECOMMENDED FOR DIAPER DERMATITIS

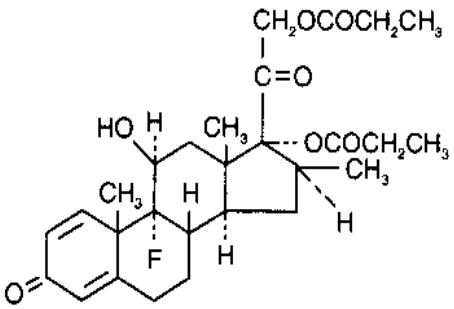
DESCRIPTION LOTRISONE Cream and Lotion contain combinations of clotrimazole, a synthetic antifungal agent, and betamethasone dipropionate, a synthetic corticosteroid, for dermatologic use.

Chemically, clotrimazole is 1–(*o*-chloro-α,α-diphenylbenzyl)imidazole, with the empirical formula $C_{22}H_{17}ClN_2$, a molecular weight of 344.84, and the following structural formula:



Clotrimazole is an odorless, white crystalline powder, insoluble in water and soluble in ethanol.

Betamethasone dipropionate has the chemical name 9-fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate, with the empirical formula $C_{28}H_{37}FO_7$, a molecular weight of 504.59, and the following structural formula:



Betamethasone dipropionate is a white to creamy white, odorless crystalline powder, insoluble in water.

Each gram of **LOTRISONE Cream** contains 10 mg clotrimazole and 0.643 mg betamethasone dipropionate (equivalent to 0.5 mg betamethasone), in a hydrophilic cream consisting of purified water, mineral oil, white petrolatum, cetyl alcohol plus stearyl alcohol, ceteareth-30, propylene glycol, sodium phosphate monobasic monohydrate, and phosphoric acid; benzyl alcohol, as preservative.

LORTISONE Cream is smooth, uniform, and white to off-white in color.

Each gram of **LOTRISONE Lotion** contains 10 mg clotrimazole and 0.643 mg betamethasone dipropionate (equivalent to 0.5 mg betamethasone), in a hydrophilic base of purified water, mineral oil, white petrolatum, cetyl alcohol plus stearyl alcohol, ceteareth-30, propylene glycol, sodium phosphate monobasic monohydrate, and phosphoric acid, benzyl alcohol as a preservative.

LOTRISONE Lotion may contain sodium hydroxide. LOTRISONE Lotion is opaque and white in color.

CLINICAL PHARMACOLOGY

Clotrimazole and Betamethasone Dipropionate

LORTISONE Cream has been shown to be least as effective as clottrimazole alone in a different cream vehicle. No comparative studies have been conducted with LOTRISONE Lotion and clotrimazole alone. Use of corticosteroids in the treatment of fungal infection may lead to suppression of host inflammation leading to worsening or decreased cure rate.

Clotrimazole

Skin penetration and systemic absorption of clotrimazole following topical application of LOTRISONE Cream or Lotion have not been studied. The following information was obtained using 1% clotrimazole cream and solution formulations. Six hours after the application of radioactive clotrimazole 1% cream and 1% solution onto intact and acutely inflamed skin, the concentration of clotrimazole varied from 100 mcg/cm^3 in the stratum corneum, to 0.5 to 1 mcg/cm^3 in the reticular dermis, and 0.1 mcg/cm^3 in the subcutis. No measurable amount of radioactivity (<0.001 mcg/mL) was found in the serum within 48 hours after

application under occlusive dressing of 0.5 mL of the solution or 0.8 g of the cream. Only 0.5% or less of the applied radioactivity was excreted in the urine.

Microbiology

Mechanism of Action: Clotrimazole is an imidazole antifungal agent. Imidazoles inhibit 14-α-demethylation of lanosterol in fungi by binding to one of the cytochrome P-450 enzymes. This leads to the accumulation of 14-α-methylsterols and reduced concentrations of ergosterol, a sterol essential for a normal fungal cytoplasmic membrane. The methylsterols may affect the electron transport system, thereby inhibiting growth of fungi.

Activity *In Vivo:* Clotrimazole has been shown to be active against most strains of the following dermatophytes, both *in vitro* and in clinical infections as described in the **INDICATIONS AND USAGE** section: *Epidermophyton floccosum, Trichophyton mentagrophytes,* and *Trichophyton rubrum.*

Activity In Vitro: In vitro, clotrimazole has been shown to have activity against most dermatophytes, **but the clinical significance of this information is unknown.**

Drug Resistance: Strains of dermatophytes having a natural resistance to clotrimazole have not been reported. Resistance to azoles including clotrimazole has been reported in some *Candida* species.

No single-step or multiple-step resistance to clotrimazole has developed during successive passages of *Trichophyton mentagrophytes*.

Betamethasone Dipropionate

Betamethasone dipropionate, a corticosteroid, has been shown to have topical (dermatologic) and systemic pharmacologic and metabolic effects characteristic of this class of drugs.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle, the integrity of the epidermal barrier and the use of occlusive dressings. (See **DOSAGE AND ADMINISTRATION** section). Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption of topical corticosteroids. Occlusive dressings

substantially increase the percutaneous absorption of topical corticosteroids (See **DOSAGE AND ADMINISTRATION** section).

Once absorbed through the skin, the pharmacokinetics of topical corticosteroids are similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

Studies performed with LOTRISONE Cream and Lotion indicate that these topical combination anti-fungal/corticosteroids may have vasoconstrictor potencies in a range that is comparable to high potency topical corticosteroids. Therefore use is not recommended in patients less than 17 years of age, in diaper dermatitis, and under occlusion.

CLINICAL STUDIES (LOTRISONE Cream)

In clinical studies of tinea corporis, tinea cruris, and tinea pedis, patients treated with LOTRISONE Cream showed a better clinical response at the first return visit than patients treated with clotrimazole cream. In tinea corporis and tinea cruris, the patient returned 3 to 5 days after starting treatment, and in tinea pedis, after 1 week. Mycological cure rates observed in patients treated with LOTRISONE Cream were as good as or better than in those patients treated with clotrimazole cream. In these same clinical studies, patients treated with LORTISONE Cream showed better clinical responses and mycological cure rates when compared with patients treated with betamethasone dipropionate cream.

CLINICAL STUDIES (LOTRISONE Lotion)

In the treatment of tinea pedis twice daily for four weeks, LOTRISONE Lotion was shown to be superior to vehicle in relieving symptoms of erythema, scaling, pruritus, and maceration at week 2. LOTRISONE Lotion was also shown to have a superior mycological cure rate compared to vehicle two weeks after discontinuation of treatment. It is unclear if the relief of symptoms at 2 weeks in this clinical study with LOTRISONE Lotion was due to the contribution of betamethasone dipropionate, clotrimazole, or both.

In the treatment of tinea cruris twice daily for two weeks, LOTRISONE Lotion was shown to be superior to vehicle in the relief of symptoms of erythema, scaling, and pruritus after 3 days. It is unclear if the relief of symptoms after 3 days in this clinical study with LOTRISONE Lotion was due to the contribution of betamethasone dipropionate, clotrimazole, or both.

The comparative efficacy and safety of LOTRISONE Lotion versus clotrimazole alone in a lotion vehicle have not been studied in the treatment of tinea pedis, tinea cruris, and tinea corporis. The comparative efficacy and safety of LOTRISONE Lotion and LOTRISONE Cream have also not been studied.

INDICATIONS AND USAGE

LOTRISONE Cream and Lotion are indicated in patients 17 years and older for the topical treatment of symptomatic inflammatory tinea pedis, tinea cruris and tinea corporis due to *Epidermophyton floccosum, Trichophyton mentagrophytes,* and *Trichophyton rubrum.* Effective treatment without the risks associated with topical corticosteroid use may be obtained using a topical antifungal agent that does not contain a corticosteroid, especially for noninflammatory tinea infections. The efficacy of LOTRISONE Cream or Lotion for the treatment of infections caused by zoophilic dermatophytes (e.g., *Microsporum canis*) has not been established. Several cases of treatment failure of Lotrisone Cream in the treatment of infections caused by *Microsporum canis* have been reported.

CONTRAINDICATIONS

LOTRISONE Cream or Lotion is contraindicated in patients who are sensitive to clotrimazole, betamethasone dipropionate, other corticosteroids or imidazoles, or to any ingredient in these preparations.

PRECAUTIONS

General: Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Conditions which augment systemic absorption include use over large surface areas, prolonged use, and use under occlusive dressings. Use of more than one corticosteriod-containing product at the same time may increase total systemic glucocorticoid exposure. Patients applying LOTRISONE Cream or Lotion to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA-axis suppression. This may be done by using the ACTH stimulation, morning plasma cortisol, and urinary free cortisol tests.

If HPA-axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids.

In a small study, LOTRISONE Cream was applied using large dosages, 7 g daily for 14 days (BID) to the crural area of normal adult subjects. Three of the eight normal subjects on whom LOTRISONE Cream was applied exhibited low morning plasma cortisol levels during treatment. One of these subjects had an abnormal Cortrosyn test. The effect on morning plasma cortisol was transient and subjects recovered one week after discontinuing dosing. In addition, two separate studies in pediatric patients demonstrated adrenal suppression as determined by cosyntropin testing (See **PRECAUTIONS – Pediatric Use** section).

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios. (See **PRECAUTIONS - Pediatric Use** section)

If irritation develops, LOTRISONE Cream or Lotion should be discontinued and appropriate therapy instituted.

THE SAFETY OF LOTRISONE CREAM OR LOTION HAS NOT BEEN DEMONSTRATED IN THE TREATMENT OF DIAPER DERMATITIS. ADVERSE EVENTS CONSISTENT WITH CORTICOSTEROID USE HAVE BEEN OBSERVED IN PATIENTS TREATED WITH LOTRISONE CREAM FOR

DIAPER DERMATITIS. THE USE OF LOTRISONE CREAM OR LOTION IN THE TREATMENT OF DIAPER DERMATITIS IS NOT RECOMMENDED.

Information for Patients: Patients using LOTRISONE Cream or Lotion should receive the following information and instructions:

1. The medication is to be used as directed by the physician and is not recommended for use longer than the prescribed time period. It is for external use only. Avoid contact with the eyes, mouth, or intravaginally.
2. This medication is to be used for the full prescribed treatment time, even though the symptoms may have improved. Notify the physician if there is no improvement after 1 week of treatment for tinea cruris or tinea corporis, or after 2 weeks for tinea pedis.
3. This medication should only be used for the disorder for which it was prescribed.
4. Other corticosteriod-containing products should not be used with LOTRISONE without first talking with your physician.
5. The treated skin area should not be bandaged, covered, or wrapped so as to be occluded. (See **DOSAGE AND ADMINISTRATION** section.)
6. Any signs of local adverse reactions should be reported to your physician.
7. Patients should avoid sources of infection or reinfection.
8. When using LOTRISONE Cream or Lotion in the groin area, patients should use the medication for two weeks only, and apply the cream or lotion sparingly. Patients should wear loose-fitting clothing. Notify the physician if the condition persists after 2 weeks.
9. The safety of LORTISONE Cream or Lotion has not been demonstrated in the treatment of diaper dermatitis. Adverse events consistent with corticosteroid use have been observed in patients treated with LOTRISONE Cream for diaper dermatitis. The use of LOTRISONE Cream or Lotion in the treatment of diaper dermatitis is not recommended.

Laboratory Tests: If there is a lack of response to LOTRISONE Cream or Lotion, appropriate confirmation of the diagnosis, including possible mycological studies, is indicated before instituting another course of therapy.

The following tests may be helpful in evaluating HPA-axis suppression due to the corticosteroid components:

Urinary free cortisol test

Morning plasma cortisol test

ACTH (cosyntropin) stimulation test

Carcinogenesis, Mutagenesis, Impairment of Fertility: There are no adequate laboratory animal studies with either the combination of clotrimazole and betamethasone dipropionate or with either component individually to evaluate carcinogenesis.

Betamethasone was negative in the bacterial mutagenicity assay (*Salmonella typhimurium* and *Escherichia coli*), and in the mammalian cell mutagenicity assay (CHO/HGPRT). It was positive in the *in vitro* human lymphocyte chromosome aberration assay, and equivocal in the *in vivo* mouse bone marrow micronucleus assay. This pattern of response is similar to that of dexamethasone and hydrocortisone.

Reproductive studies with betamethasone dipropionate carried out in rabbits at doses of 1.0 mg/kg by the intramuscular route and in mice up to 33 mg/kg by the intramuscular route indicated no impairment of fertility except for dose-related increases in fetal resorption rates in both species. These doses are approximately 5- and 38- fold the maximum human dose based on body surface areas, respectively.

In a combined study of the effects of clotrimazole on fertility, teratogenicity, and postnatal development, male and female rats were dosed orally (diet admixture) with levels of 5, 10, 25, or 50 mg/kg/day (approximately 1-8 times the maximum dose in a 60 kg adult based on body surface area) from 10 weeks prior to mating until 4 weeks postpartum. No adverse effects on the duration of estrous cycle, fertility, or duration of pregnancy were noted.

Pregnancy: Teratogenic Effects: Pregnancy Category C: There have been no teratogenic studies performed in animals or humans with the combination of clotrimazole and betamethasone dipropionate. Corticosteriods are generally

teratogenic in laboratory animals when administered at relatively low dosage levels.

Studies in pregnant rats with intravaginal doses up to 100 mg/kg (15 times the maximum human dose) revealed no evidence of fetotoxicity due to clotrimazole exposure.

No increase in fetal malformations was noted in pregnant rats receiving oral (gastric tube) clotrimazole doses up to 100 mg/kg/day during gestation days 6-15. However, clotrimazole dosed at 100 mg/kg/day was embryotoxic (increased resorptions), fetotoxic (reduced fetal weights) and maternally toxic (reduced body weight gain) to rats. Clotrimazole dosed at 200 mg/kg/day (30 times the maximum human dose) was maternally lethal, and therefore fetuses were not evaluated in this group. Also in this study, doses up to 50 mg/kg/day (8 times the maximum human dose) had no adverse effects on dams or fetuses. However, in the combined fertility, teratogenicity, and postnatal development study described above, 50 mg/kg clotrimazole, was associated with reduced maternal weight gain and reduced numbers of offspring reared to 4 weeks.

Oral clotrimazole doses of 25, 50, 100, and 200 mg/kg/day (2-15 times the maximum human dose) were not teratogenic in mice. No evidence of maternal toxicity or embryotoxicity was seen in pregnant rabbits dosed orally with 60, 120, or 180 mg/kg/day (18-55 times the maximum human dose).

Betamethasone dipropionate has been shown to be teratogenic in rabbits when given by the intramuscular route at doses of 0.05 mg/kg. This dose is approximately one-fifth the maximum human dose. The abnormalities observed included umbilical hernias, cephalocele and cleft palates.

Betamethasone dipropionate has not been tested for teratogenic potential by the dermal route of administration. Some corticosteroids have been shown to be teratogenic after dermal application to laboratory animals.

There are no adequate and well-controlled studies in pregnant women of the teratogenic effects of topically applied corticosteroids. Therefore, Lotrisone Cream or Lotion should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroids production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to product detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when LOTRISONE Cream or Lotion is administered to a nursing woman.

Pediatric Use: Adverse events consistent with corticosteroid use have been observed in patients under 12 years of age treated with LOTRISONE Cream. In open-label studies, 17 of 43 (39.5%) evaluable pediatric patients (aged 12 to 16 years old) using LOTRISONE Cream for treatment of tinea pedis demonstrated adrenal suppression as determined by cosyntropin testing. In another open-label study, 8 of 17 (47.1%) evaluable pediatric patients (aged 12 to 16 years old) using LOTRISONE Cream for treatment of tinea cruris demonstrated adrenal suppression as determined by cosyntropin testing. **THE USE OF LOTRISONE CREAM OR LOTION IN THE TREATMENT OF PATIENTS UNDER 17 YEARS OF AGE OR PATIENTS WITH DIAPER DERMATITIS IS NOT RECOMMENDED.**

Because of higher ratio of skin surface area to body mass, pediatric patients under the age of 12 years are at a higher risk with LOTRISONE Cream or Lotion. The studies described above suggest that pediatric patients under the age of 17 years may also have this risk. They are at increased risk of developing Cushing's syndrome while on treatment and adrenal insufficiency after withdrawal of treatment. Adverse effects, including striae and growth retardation, have been reported with inappropriate use of LOTRISONE Cream in infants and children (see **PRECAUTIONS** and **ADVERSE REACTIONS** sections).

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Geriatric Use: Clinical studies of LOTRISONE Cream or Lotion did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Post-market adverse events reporting for LOTRISONE Cream in patients aged 65 and above includes reports of skin atrophy and rare reports of skin ulceration. Caution should be exercised with the use of these corticosteroid containing topical products on thinning skin. **THE USE OF LOTRISONE CREAM OR LOTION UNDER OCCLUSION, SUCH AS IN DIAPER DERMATITIS, IS NOT RECOMMENDED.**

ADVERSE REACTIONS

Adverse reactions reported for LOTRISONE Cream in clinical trials were paresthesia in 1.9% of patients, and rash, edema, and secondary infection, each in 1% of patients.

Adverse reactions reported for LOTRISONE Lotion in clinical trials were burning and dry skin in 1.6% of patients and stinging is less than 1% of patients.

The following local adverse reactions have been reported with topical corticosteroids and may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria. In the pediatric population, reported adverse events for LOTRISONE Cream include growth retardation, benign intracranial hypertension, Cushing's syndrome (HPA axis suppression), and local cutaneous reactions, including skin atrophy.

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Adverse reactions reported with the use of clotrimazole are as follows: erythema, stinging, blistering, peeling, edema, pruritus, urticaria and general irritation of the skin.

OVERDOSAGE

Amounts greater than 45 g/week of LOTRISONE Cream or 45 mL/week of LOTRISONE Lotion should not be used. Acute overdosage with topical application of LOTRISONE Cream or Lotion is unlikely and would not be expected to lead to life-threatening situation. LOTRISONE Cream or Lotion should not be used for longer than the prescribed time period.

Topically applied corticosteroids, such as the one contained in LOTRISONE Cream or Lotion can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS** section).

DOSAGE AND ADMINISTRATION

Gently massage sufficient LOTRISONE Cream or Lotion into the affected skin areas twice a day, in the morning and evening.

LOTRISONE Cream or Lotion should <u>not</u> be used longer than 2 weeks in the treatment of tinea corporis or tinea cruris, and amounts greater than 45 g per week of LOTRISONE Cream or amounts greater than 45 mL per week of LOTRISONE Lotion should not be used. If a patient with tinea corporis or tinea cruris shows no clinical improvement after one week of treatment with LOTRISONE Cream or Lotion, the diagnosis should be reviewed.

LOTRISONE Cream or Lotion should <u>not</u> be used longer than 4 weeks in the treatment of tinea pedis and amounts greater than 45 g per week of LOTRISONE Cream or amounts greater than 45 mL per week of LOTRISONE Lotion should not be used. If a patient with tinea pedis shows no clinical improvement after 2 weeks of treatment with LOTRISONE Cream or Lotion, the diagnosis should be reviewed.

LOTRISONE Cream or Lotion should not be used with occlusive dressings.

HOW SUPPLIED

LOTRISONE Cream is supplied in 15-gram (NDC 0085-0924-01) and 45-gram tubes (NDC 0085-0924-02); boxes of one. **Store between 2°C and 30°C (36°F and 86°F).**

LOTRISONE Lotion is supplied in 30-mL bottles (NDC 0085-0809-01), box of one. **Store 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 EACH USE.

Rx only

Manufactured by: Schering/KEY

Schering Corporation/KEY Pharmaceuticals, Inc.

Kenilworth, NJ 07033 USA

3/10/03

TEAR AT PERFORATION

GIVE TO PATIENT

Patient's Instructions for Use

SHAKE WELL BEFORE EACH USE

LOTRISONE® Cream, USP
LOTRISONE® Lotion
(clotrimazole, USP and betamethasone dipropionate, USP)

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 message 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 corticosteriod-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 two 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 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, 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 between 2° and 30°C (36° and 86°F).

LOTRISONE Lotion should only be stored in an upright position 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

Schering/Key

Schering Corporation/Key Pharmaceuticals

Kenilworth, NJ 07033

470 3/10/03