HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ELOCON lotion safely and effectively. See full prescribing information for ELOCON lotion.

ELOCON® (mometasone furoate) lotion, for topical use
Initial U.S. Approval: 1987

----------INDICATIONS AND USAGE----------
ELOCON lotion is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in adults and pediatric patients 12 years of age and older. (1)

---------- DOSAGE AND ADMINISTRATION ----------
- For topical use only. Not for oral, ophthalmic, or intravaginal use. (2)
- Apply a few drops to the affected skin areas and massage lightly until it disappears once daily. (2)
- Discontinue therapy when control is achieved. (2)
- If no improvement is seen within 2 weeks, reassess diagnosis. (2)
- Do not use with occlusion. (2)

---------- DOSAGE FORMS AND STRENGTHS ----------
Lotion, 0.1%. (3)

----------CONTRAINDICATIONS----------
ELOCON lotion is contraindicated in those patients with a history of hypersensitivity to mometasone furoate or any of the excipients in ELOCON lotion. (4)

---------- WARNINGS AND PRECAUTIONS ----------
- Endocrine System Adverse Reactions:
  - Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur with the potential for glucocorticosteroid insufficiency. (5.1)
  - Consider periodic evaluations for HPA axis suppression if ELOCON cream is applied to a large surface area, to areas under occlusion, for prolonged duration or on altered skin barriers. If HPA axis suppression occurs, withdraw ELOCON lotion, reduce the application frequency, or consider switching to a less potent corticosteroid. (5.1, 8.4)
  - Cushing's syndrome, hyperglycemia and glucosuria may occur due to systemic absorption. (5.1, 8.4)
  - Pediatric patients may be more susceptible to systemic toxicity. (5.1, 8.4)
- Ophthalmic Adverse Reactions: May increase the risk of cataracts and glaucoma. If visual symptoms occur, consider referral to an ophthalmologist. (5.2)

---------- ADVERSE REACTIONS ----------
Most common adverse reactions included are acneiform reaction, burning, itching and folliculitis. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Organon LLC, a subsidiary of Organon & Co., at 1-844-674-3200 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 7/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ELOCON® lotion is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in adults and pediatric patients 12 years of age or older.

2 DOSAGE AND ADMINISTRATION

- ELOCON lotion is for topical use only. It is not for oral, ophthalmic, or intravaginal use.
- Apply a few drops of ELOCON lotion to the affected skin areas and massage lightly until it disappears once daily. Avoid use on the face, groin, or axillae. Wash hands after each application.
- Avoid contact with eyes *[see Warnings and Precautions (5.2)]*.
- Do not use ELOCON lotion with occlusion. Do not use ELOCON lotion in the treatment of diaper dermatitis.
- Discontinue therapy when control is achieved.
- If no improvement is seen within 2 weeks, consider reassessment of diagnosis *[see Warnings and Precautions (5.1)]*.

3 DOSAGE FORMS AND STRENGTHS

Lotion, 0.1%. Each gram of ELOCON lotion contains 1 mg of mometasone furoate in a colorless, clear to translucent lotion base.

4 CONTRAINDICATIONS

ELOCON lotion is contraindicated in patients with a history of hypersensitivity to mometasone furoate or any of the excipients in ELOCON lotion.

5 WARNINGS AND PRECAUTIONS

5.1 Endocrine System Adverse Reactions

Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression

Systemic absorption of topical corticosteroids, including ELOCON lotion, can cause reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or after withdrawal of treatment. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of high potency corticosteroids, large treatment surface areas, prolonged use, use of occlusive dressing, altered skin barrier, liver failure and young age.

Because of the potential for systemic absorption, consider evaluating patients who are at risk of HPA axis suppression periodically for evidence of HPA axis suppression. This may be done by using the adrenocorticotropic hormone (ACTH) stimulation test.

In a trial evaluating the effects of mometasone furoate lotion on the HPA axis, 15 mL were applied without occlusion twice daily (30 mL per day) for 7 days to 4 adult subjects with scalp and body psoriasis. At the end of treatment, the plasma cortisol levels for each of the 4 subjects remained within the normal range and changed little from baseline *[see Clinical Pharmacology (12.2)]*.

If HPA axis suppression occurs, gradually withdraw ELOCON lotion,reduce the frequency of application or consider use of a less potent corticosteroid. If signs and symptoms glucocorticosteroid insufficiency occur, supplemental systemic corticosteroids may be required.

Cushing's Syndrome, Hyperglycemia, and Glucosuria

Systemic effects of topical corticosteroids, including ELOCON lotion, may also manifest as Cushing's syndrome, hyperglycemia, and glucosuria.

Additional Considerations

Concomitant use of ELOCON lotion with other corticosteroid-containing products may increase total systemic corticosteroid exposure, and result in an increased risk for adverse reactions.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios *[see Use in Specific Populations (8.4)]*.

Minimize the risk of adverse reactions by using ELOCON lotion as recommended *[see Dosage and Administration (2)]*.

5.2 Ophthalmic Adverse Reactions

Use of topical corticosteroids, including ELOCON lotion, may increase the risk of posterior subcapsular cataracts and glaucoma. Cataracts and glaucoma have been reported in postmarketing experience with the use of topical corticosteroid products, including topical mometasone products *[see Adverse Reactions (6.2)].*

Avoid contact of ELOCON lotion with eyes. Advise patients to report any visual symptoms and consider referral to an ophthalmologist for evaluation.

5.3 Allergic Contact Dermatitis

Use of topical corticosteroids, including ELOCON lotion, can cause allergic contact dermatitis. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Corroborate such an observation with appropriate diagnostic patch testing. If irritation develops, discontinue ELOCON lotion and institute appropriate therapy.

5.4 Concomitant Skin Infections

Use of topical corticosteroids, including ELOCON lotion, may delay healing or worsen concomitant skin infections. If concomitant skin infections are present or develop, use an appropriate antimicrobial agent. If a favorable response does not occur promptly, gradually withdraw ELOCON lotion and discontinue use until the infection has been adequately controlled.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed in more detail in other sections of the labeling:

- Endocrine System Adverse Reactions *[see Warnings and Precautions (5.1), Use in Specific Populations (8.4)]*
- Ophthalmic Adverse Reactions *[see Warnings and Precautions (5.2)]*
- Allergic Contact Dermatitis *[see Warnings and Precautions (5.3)]*
- Concomitant Skin infections *[see Warnings and Precautions (5.4)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In clinical trials involving 209 subjects, the incidence of adverse reactions associated with the use of ELOCON lotion was 3%. Reported reactions included acneiform reaction, 2; burning, 4; and itching, 1. In an irritation/sensitization study involving 156 normal subjects, the incidence of folliculitis was 3% (4 subjects).

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of topical corticosteroids. Because adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- *Endocrine Disorders:* Cushing's syndrome, linear growth retardation, and delayed weight gain.
- *Local Adverse Reactions:* irritation, dryness, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae, and miliaria.
- *Nervous System Disorders:* intracranial hypertension.
- *Ophthalmic Adverse Reactions:* blurred vision, cataracts, glaucoma, and increased intraocular pressure.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled studies in pregnant women. Available data from postmarketing reports and published observational studies over decades of use with mometasone furoate use during pregnancy have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal outcomes. Maternal use of potent or very potent topical corticosteroids may be associated with an increased risk of low birth weight infants *(see Data)*. Advise pregnant women to use ELOCON lotion on the smallest area of skin and for the shortest duration possible.

When administered subcutaneously, orally, or topically to pregnant rats, rabbits, and mice, mometasone furoate increased fetal malformations. The doses that produced malformations also decreased fetal growth, as measured by lower fetal weights and/or delayed ossification. Mometasone furoate also caused dystocia and related complications when administered to rats during the end of pregnancy *(see Data)*. The available data do not allow the calculation of relevant comparisons between the systemic exposure of mometasone furoate observed in animal studies to the systemic exposure that would be expected in humans after topical use of ELOCON lotion.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Human Data

Published data from one observational study that included 60,497 pregnancies exposed to topical corticosteroids, including 10,056 pregnancies exposed to topical mometasone, did not identify an increased risk of low birth weight infants. However, data from other observational studies demonstrate that maternal use of potent to very potent topical corticosteroids was associated with an increased risk of low birth weight infants, especially when the cumulative dosage throughout pregnancy was greater than 300 grams. Available studies have limitations including confounding by disease severity, imprecision in birth weight outcomes, and data reliance on filled prescriptions rather than actual use.

Animal Data

In mice, mometasone furoate caused cleft palate at subcutaneous doses of 60 mcg/kg and above. Fetal survival was reduced at 180 mcg/kg. No toxicity was observed at 20 mcg/kg.

In rats, mometasone furoate produced umbilical hernias at topical doses of 600 mcg/kg and above. Mometasone furoate produced delays in ossification, but no malformations at 300 mcg/kg.

In rabbits, mometasone furoate caused multiple malformations (e.g., flexed front paws, gallbladder agenesis, umbilical hernia, hydrocephaly) at topical doses of 150 mcg/kg and above. In an oral study, mometasone furoate increased resorptions and caused cleft palate and/or head malformations (hydrocephaly and domed head) at 700 mcg/kg. At 2800 mcg/kg most litters were aborted or resorbed. No toxicity was observed at 140 mcg/kg.

When rats received subcutaneous doses of mometasone furoate throughout pregnancy or during the later stages of pregnancy, prolonged and difficult labor and reduced the number of live births, birth weight, and early pup survival were observed at 15 mcg/kg. Similar effects were not observed at 7.5 mcg/kg.

8.2 Lactation

Risk Summary

There are no data on the presence of mometasone furoate following topical administration in animal or human milk, the effects on the breastfed infant, or the effects on milk production. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. To minimize potential exposure to the breastfed infant via breast milk, use ELOCON lotion on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply ELOCON lotion directly to the nipple and areola to avoid direct infant exposure *[see Warnings and Precautions (5.1) and Use in Specific Populations (8.4)]*. The

developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ELOCON lotion and any potential adverse effects on the breastfed infant from ELOCON lotion or from the underlying maternal condition.

8.4 Pediatric Use

The safety and efficacy of ELOCON lotion for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses have been established in pediatric patients 12 years of age and older.

The safety and efficacy of ELOCON lotion have not been established in pediatric patients younger than 12 years of age.

The following adverse reactions were reported to be possibly or probably related to treatment with ELOCON lotion during a clinical trial in 14% of 65 pediatric subjects 6 months to 2 years of age: decreased glucocorticoid levels, 4; paresthesia, 2; dry mouth,1; an unspecified endocrine disorder, 1; pruritus, 1; and an unspecified skin disorder, 1. The following signs of skin atrophy were also observed among 65 subjects treated with ELOCON lotion in a clinical trial: shininess, 4; telangiectasia, 2; loss of elasticity, 2; and loss of normal skin markings, 3.

Endocrine Adverse Reactions

Sixty-five pediatric subjects ages 6 to 23 months, with atopic dermatitis, were enrolled in an open-label, HPA axis safety trial. ELOCON lotion caused HPA axis suppression in approximately 29% of pediatric subjects ages 6 to 23 months, who showed normal adrenal function by Cortrosyn test before starting treatment, and applied ELOCON over a mean body surface area of 40% (range 16%-90%). The criteria for suppression were: basal cortisol level of ≤5 mcg/dL, 30-minute post-stimulation level of ≤18 mcg/dL, or an increase of <7 mcg/dL. Follow-up testing 2 to 4 weeks after stopping treatment, available for 8 of the subjects, demonstrated suppressed HPA axis function in 1 subject, using these same criteria. ELOCON lotion is not indicated for use in pediatric patients younger than 12 years of age *[see Clinical Pharmacology (12.2)]*.

Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are, therefore, also at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Pediatric patients may be more susceptible than adults to skin atrophy, including striae, when they are treated with topical corticosteroids.

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

Do not use ELOCON lotion in the treatment of diaper dermatitis.

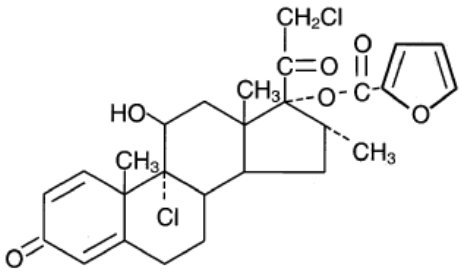
8.5 Geriatric Use

Clinical trials of ELOCON lotion did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious usually starting at the low end of the dosing range.

11 DESCRIPTION

ELOCON (mometasone furoate) lotion, 0.1% contains 1 mg mometasone furoate per gram in a colorless, clear to translucent lotion base for topical use. Mometasone furoate is a synthetic corticosteroid with anti-inflammatory activity.

Chemically, mometasone furoate is 9α, 21-dichloro-11β,17-dihydroxy-16α-methylpregna-1,4-diene-3,20-dione 17-(2-furoate), with the empirical formula $C_{27}H_{30}Cl_2O_6$, a molecular weight of 521.4 and the following structural formula:



Mometasone furoate is a white to off-white powder practically insoluble in water, slightly soluble in octanol, and moderately soluble in ethyl alcohol.

ELOCON lotion contains the following inactive ingredients: hydroxypropyl cellulose, isopropyl alcohol (40%), propylene glycol, purified water and sodium phosphate monobasic monohydrate. May also contain phosphoric acid used to adjust the pH to approximately 4.5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the precise mechanism of action in dermatoses is unknown.

12.2 Pharmacodynamics

Studies performed with ELOCON lotion indicate that it is in the medium range of potency as compared with other topical corticosteroids.

Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression

In a study evaluating the effects of mometasone furoate lotion on the HPA axis, 15 mL were applied without occlusion twice daily (30 mL per day) for 7 days to 4 adult subjects with scalp and body psoriasis. At the end of treatment, the plasma cortisol levels for each of the 4 subjects remained within the normal range and changed little from baseline *[see Warnings and Precautions (5.1)]*.

Sixty-five pediatric subjects ages 6 to 23 months, with atopic dermatitis, were enrolled in an open-label, HPA axis safety trial. ELOCON lotion was applied once daily over a mean body surface area of 40% (range 16%-90%). In approximately 29% of subjects who showed normal adrenal function by Cortrosyn test before starting treatment, adrenal suppression was observed at the end of treatment with ELOCON lotion. The criteria for suppression were: basal cortisol level of ≤5 mcg/dL, 30-minute post-stimulation level of ≤18 mcg/dL, or an increase of <7 mcg/dL. Follow-up testing 2 to 4 weeks after stopping treatment, available for 8 of the subjects, demonstrated suppressed HPA axis function in 1 subject, using these same criteria *[see Use in Specific Populations (8.4)]*.

12.3 Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Studies in humans indicate that approximately 0.7% of the applied dose of ELOCON ointment enters the circulation after 8 hours of contact on normal skin without occlusion. A similar minimal degree of absorption of the corticosteroid from the lotion formulation would be anticipated. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of ELOCON lotion. Long-term carcinogenicity studies of mometasone furoate were conducted by the inhalation route in rats and mice. In a 2-year carcinogenicity study in Sprague Dawley rats, mometasone furoate demonstrated no statistically significant increase of tumors at inhalation doses up to 67 mcg/kg. In a 19-month carcinogenicity study in Swiss CD-1 mice, mometasone furoate demonstrated no statistically significant increase in the incidence of tumors at inhalation doses up to 160 mcg/kg.

Mometasone furoate increased chromosomal aberrations in an *in vitro* Chinese hamster ovary cell assay, but did not increase chromosomal aberrations in an *in vitro* Chinese hamster lung cell assay. Mometasone furoate was not mutagenic in the Ames test or mouse lymphoma assay, and was not clastogenic in an *in vivo* mouse micronucleus assay, a rat bone marrow chromosomal aberration assay, or a mouse male germ-cell chromosomal aberration assay. Mometasone furoate also did not induce unscheduled DNA synthesis *in vivo* in rat hepatocytes.

In reproductive studies in rats, mometasone furoate did not cause impairment of fertility in male or female rats at subcutaneous doses up to 15 mcg/kg.

14 CLINICAL STUDIES

The safety and efficacy of ELOCON lotion, 0.1% for the treatment of corticosteroid-responsive dermatoses was demonstrated in two vehicle-controlled trials, one in subjects with psoriasis of the scalp and one in subjects with seborrheic dermatitis. A total of 405 subjects (age range: 12-95 years) received ELOCON lotion (205 subjects) or the vehicle lotion applied once daily for 21 days.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

ELOCON lotion is colorless, clear to translucent and supplied in 30-mL (27.5 gram) (NDC XXXXX-XXX-XX) and 60-mL (55 gram) (NDC XXXXX-XXX-XX) bottles; boxes of one.

Storage and Handling

Store ELOCON lotion, 0.1% at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Administration Instructions

Inform patients of the following *[see Dosage and Administration (2)]*:

- Use ELOCON lotion as directed by the healthcare provider. It is for external use only. Wash hands after use.
- Discontinue therapy when control is achieved. If no improvement is seen within 2 weeks, contact the healthcare provider.
- Avoid contact with the eyes.
- Avoid using ELOCON lotion on the face, underarms, or groin areas.
- Do not bandage or otherwise cover or wrap the treated skin area so as to be occlusive. Do not use ELOCON lotion in the treatment of diaper dermatitis.

Endocrine System Adverse Reactions

- Advise patients that ELOCON lotion may cause HPA axis suppression. Inform patients that use of topical corticosteroids, including ELOCON lotion, may require periodic evaluation for HPA axis suppression. Topical corticosteroids may have other endocrine effects. Instruct patients not to use other corticosteroid-containing products while using ELOCON cream without first consulting their healthcare provider *[see Warnings and Precautions (5.1)]*.

Ophthalmic Adverse Reactions

- Advise patients to report any visual symptoms to their healthcare provider *[see Warnings and Precautions (5.2)].*

Allergic Contact Dermatitis

- Advise patients to report any signs allergic contact dermatitis to their healthcare provider *[see Warnings and Precautions (5.3)].*

Pregnancy and Lactation

- Advise patients that may become pregnant to use ELOCON lotion on the smallest area of skin and for the shortest duration possible while pregnant or breastfeeding. Advise breastfeeding patients not to apply ELOCON lotion directly to the nipple and areola to avoid direct infant exposure *[see Use in Specific Populations (8.1, 8.2)]*.

Distributed by: Organon LLC, a subsidiary of
ORGANON & Co.,
Jersey City, NJ 07302, USA

For patent information: www.organon.com/our-solutions/patent/

uspi-og0887-lt-XXXXr000

Patient Information
ELOCON® (El-oh-con)
(mometasone furoate) lotion

Important information: ELOCON lotion is for use on skin only (topical). Do not use ELOCON lotion in your eyes, mouth, or vagina.

What is ELOCON lotion?

- ELOCON lotion is a prescription medicine used on the skin (topical) for the relief of redness, swelling, heat, pain (inflammation) and itching, caused by certain skin problems in adults and children 12 years of age or older.
- It is not known if ELOCON lotion is safe and effective for use in children under 12 years of age.
- ELOCON lotion is not recommended for use in children under 12 years of age.

Do not use ELOCON lotion if you:

- are allergic to mometasone furoate or any of the ingredients in ELOCON lotion. See the end of this leaflet for a complete list of ingredients in ELOCON lotion.

Before using ELOCON lotion, tell your healthcare provider about all your medical conditions, including if you:

- have had irritation or other skin reaction to a steroid medicine in the past.
- have a skin infection at the site to be treated. You may need medicine to treat the skin infection before using ELOCON lotion.
- have thinning of the skin (atrophy) at the treatment site.
- have diabetes.
- have adrenal gland problems.
- have liver problems.
- are pregnant or plan to become pregnant. It is not known if ELOCON lotion will harm your unborn baby. If you use ELOCON lotion during pregnancy, use ELOCON lotion on the smallest area of the skin and for the shortest time needed.
- are breastfeeding or plan to breastfeed. It is not known if ELOCON lotion passes into your breast milk. If you use ELOCON lotion and breastfeed, use ELOCON lotion on the smallest area of the skin and for the shortest time needed. Do not apply ELOCON lotion directly to the nipple and areola to avoid contact with your baby.

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. Do not use other products containing a corticosteroid medicine while using ELOCON lotion without talking to your healthcare provider first.

How should I use ELOCON lotion?

- Use ELOCON lotion exactly as your healthcare provider tells you to use it.
- Apply a few drops of ELOCON lotion to the affected skin area 1 time each day and rub it in lightly until it disappears.
- Use ELOCON lotion until the affected skin area is improved. Tell your healthcare provider if the treated skin area does not get better after 2 weeks of treatment.
- Do not bandage, cover, or wrap the treated skin area unless your healthcare provider tells you to.
- ELOCON lotion should not be used to treat diaper rash or redness. Avoid using ELOCON lotion in the diaper area if wearing diapers or plastic pants.
- Avoid using ELOCON lotion on the face, groin, or underarms (armpits).
- Wash your hands after applying ELOCON lotion.

What are the possible side effects of ELOCON lotion?

ELOCON lotion may cause serious side effects, including:

- **ELOCON lotion can pass through your skin**. Too much ELOCON lotion passing through your skin can cause your adrenal glands to stop working properly. Your healthcare provider may do blood tests to check for adrenal gland problems.
- **Cushing's syndrome**, a condition that happens when your body is exposed to too much of the hormone cortisol.
- **High blood sugar (hyperglycemia)**.

- **Effects on growth and weight in children**.
- **Vision problems.** Topical corticosteroids, including ELOCON lotion, may increase your chance of developing vision problems such as cataract and glaucoma. Tell your healthcare provider if you develop blurred vision or other vision problems during treatment with ELOCON lotion.
- **Skin problems.** Skin problems may happen during treatment with ELOCON lotion, including allergic reactions (contact dermatitis) and skin infections at the treatment site. Stop using ELOCON lotion and tell your healthcare provider if you develop any skin reactions such as pain, tenderness, swelling, or problems healing during treatment with ELOCON lotion.

The most common side effects of ELOCON lotion include burning, itching, and inflammation of the hair follicle (folliculitis).

These are not all the possible side effects of ELOCON lotion.

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 ELOCON lotion?

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

General information about the safe and effective use of ELOCON lotion.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ELOCON lotion for a condition for which it was not prescribed. Do not give ELOCON lotion 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 ELOCON lotion that is written for health professionals.

What are the ingredients in ELOCON lotion?

Active ingredient: mometasone furoate

Inactive ingredients: hydroxypropyl cellulose, isopropyl alcohol (40%), propylene glycol, purified water and sodium phosphate monobasic monohydrate. May also contain phosphoric acid used to adjust the pH to approximately 4.5.

Distributed by: Organon LLC, a subsidiary of
ORGANON & Co.,
Jersey City, NJ 07302, USA

For patent information: www.organon.com/our-solutions/patent/

usppi-og0887-lt-XXXXrXXX

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: July 2026