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

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

----------INDICATIONS AND USAGE----------
ELOCON ointment is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in adults and pediatric patients 2 years of age and older. (1)

---------- DOSAGE AND ADMINISTRATION ----------
- For topical use only. Not for oral, ophthalmic, or intravaginal use. (2)
- Apply a thin film to the affected skin areas 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 ----------
Ointment, 0.1%. (3)

----------CONTRAINDICATIONS----------
ELOCON ointment is contraindicated in patients with a history of hypersensitivity to mometasone furoate or any of the excipients in ELOCON ointment. (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 ointment, 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: Topical corticosteroids 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 are burning, pruritus, skin atrophy, tingling/stinging and furunculosis. (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® ointment is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in adults and pediatric patients 2 years of age or older.

2 DOSAGE AND ADMINISTRATION

- ELOCON ointment is for topical use only. It is not for oral, ophthalmic, or intravaginal use.
- Apply a thin film of ELOCON ointment to the affected skin areas 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 ointment with occlusion. Do not use ELOCON ointment 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

Ointment, 0.1%. Each gram of ELOCON ointment contains 1 mg of mometasone furoate in a white to off-white uniform ointment base.

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Endocrine System Adverse Reactions

Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression

Systemic absorption of topical corticosteroids, including ELOCON ointment, 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 dressings, altered skin barrier, liver failure, and young age.

Because of the potential for systemic absorption, consider periodically evaluating patients who are at risk of HPA axis suppression 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 ointment on the HPA axis, 15 grams were applied twice daily for 7 days to 6 adult subjects with psoriasis or atopic dermatitis. In this trial, mometasone furoate ointment caused a slight lowering of adrenal corticosteroid secretion *[see Clinical Pharmacology (12.2)]*.

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

Cushing's Syndrome, Hyperglycemia, and Glucosuria

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

Additional Considerations

Concomitant use of ELOCON ointment with other corticosteroid-containing products may increase total systemic corticosteroid exposure, and result in 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 ointment as recommended *[see Dosage and Administration (2)]*.

5.2 Ophthalmic Adverse Reactions

Use of topical corticosteroids, including ELOCON ointment, 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 ointment 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 ointment, 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 ointment and institute appropriate therapy.

5.4 Concomitant Skin Infections

Use of topical corticosteroids, including ELOCON ointment, 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 ointment 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 controlled clinical trials the incidence of adverse reactions associated with the use of ELOCON ointment was 4.8%. Reported reactions included burning, pruritus, skin atrophy, tingling/stinging, and furunculosis. Cases of rosacea associated with the use of ELOCON ointment have been reported.

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, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, 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 ointment 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 ointment.

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 ointment on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply ELOCON ointment 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 ointment and any potential adverse effects on the breastfed infant from ELOCON ointment or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of ELOCON ointment for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses have been established in pediatric patients 2 years of age or older *[see Adverse Reactions (6.1)]*.

The safety and efficacy of ELOCON ointment have not been established in pediatric patients younger than 2 years of age. The safety and efficacy of ELOCON ointment use for longer than three weeks have not been established in pediatric patients 2 years of age and older.

The following adverse reactions were reported to be possibly or probably related to treatment with ELOCON ointment during a clinical study in 5% of 63 pediatric subjects 6 months to 2 years of age: decreased glucocorticoid levels, 1; an unspecified skin disorder, 1; and a bacterial skin infection, 1. The following signs of skin atrophy were also observed among 63 subjects treated with ELOCON ointment in a clinical trial: shininess, 4; telangiectasia, 1; loss of elasticity, 4; loss of normal skin markings, 4; and thinness, 1.

Endocrine Adverse Reactions

Sixty-three pediatric subjects ages 6 to 23 months, with atopic dermatitis, were enrolled in an open-label HPA axis safety trial. ELOCON ointment caused HPA axis suppression in approximately 27% 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 39% (range 15%-99%). 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 3 subjects, using these same criteria. ELOCON ointment is not indicated for use in pediatric patients younger than 2 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 glucocorticosteroid 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 ointment in the treatment of diaper dermatitis.

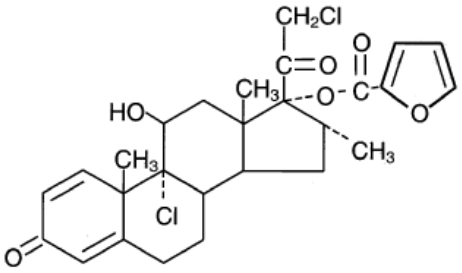
8.5 Geriatric Use

Clinical trials of ELOCON ointment included 310 subjects who were 65 years of age and over and 57 subjects who were 75 years of age and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

11 DESCRIPTION

ELOCON (mometasone furoate) ointment, 0.1% contains 1 mg mometasone furoate per gram in a white to off-white uniform ointment 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 ointment contains the following inactive ingredients: hexylene glycol, phosphoric acid, propylene glycol stearate (55% monoester), purified water, white wax, and white petrolatum.

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 ointment 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 ointment on the HPA axis, 15 grams were applied twice daily for 7 days to 6 adult subjects with psoriasis or atopic dermatitis. The ointment was applied without occlusion to at least 30% of the body surface. The results showed that the drug caused a slight lowering of adrenal corticosteroid secretion *[see Warnings and Precautions (5.1)]*.

Sixty-three pediatric subjects ages 6 to 23 months, with atopic dermatitis, were enrolled in an open-label HPA axis safety study. ELOCON ointment was applied once daily over a mean body surface area of 39% (range 15%-99%). In approximately 27% of subjects who showed normal adrenal function by Cortrosyn test before starting treatment, adrenal suppression was observed at the end of treatment with ELOCON ointment. 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 3 subjects, 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. 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 ointment. 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 ointment, 0.1% for the treatment of corticosteroid-responsive dermatoses was demonstrated in two vehicle-controlled trials, one in subjects with psoriasis and one in subjects with atopic dermatitis. These trials included a total of 218 subjects with 109 subjects applying ELOCON ointment and 109 subjects applying vehicle ointment once daily for 21 days.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

ELOCON ointment is a white to off-white uniform ointment and supplied in 15-gram (NDC XXXXX-XXX-XX) and 45-gram (NDC XXXXX-XXX-XX) tubes; boxes of one.

Storage and Handling

Store 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).

Important Administration Instructions

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

- Use ELOCON ointment 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 ointment 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 ointment in the treatment of diaper dermatitis.

Endocrine System Adverse Reactions

- Advise patients that ELOCON ointment may cause HPA axis suppression. Inform patients that use of topical corticosteroids, including ELOCON ointment, 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 of 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 ointment on the smallest area of skin and for the shortest duration possible while pregnant or breastfeeding. Advise breastfeeding patients not to apply ELOCON ointment 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/

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

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

What is ELOCON ointment?

- ELOCON ointment 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 2 years of age or older.
- It is not known if ELOCON ointment is safe and effective for use in children under 2 years of age.
- ELOCON ointment is not recommended for use in children under 2 years of age.

Do not use ELOCON ointment if you:

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

Before using ELOCON ointment, 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 ointment will harm your unborn baby. If you use ELOCON ointment during pregnancy, use ELOCON ointment 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 ointment passes into your breast milk. If you use ELOCON ointment and breastfeed, use ELOCON ointment on the smallest area of the skin and for the shortest time needed. Do not apply ELOCON ointment 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 ointment without talking to your healthcare provider first.

How should I use ELOCON ointment?

- Use ELOCON ointment exactly as your healthcare provider tells you to use it.
- Apply a thin film of ELOCON ointment to the affected skin area 1 time each day.
- Use ELOCON ointment 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 ointment should not be used to treat diaper rash or redness. Do not apply ELOCON ointment in the diaper area if wearing diapers or plastic pants.
- Avoid using ELOCON ointment on the face, groin, or underarms (armpits).
- Wash your hands after applying ELOCON ointment.

What are the possible side effects of ELOCON ointment?

ELOCON ointment may cause serious side effects, including:

- **ELOCON ointment can pass through your skin**. Too much ELOCON ointment 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 ointment, 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 ointment.
- **Skin problems.** Skin problems may happen during treatment with ELOCON ointment, including allergic reactions (contact dermatitis) and skin infections at the treatment site. Stop using ELOCON ointment and tell your healthcare provider if you develop any skin reactions such as pain, tenderness, swelling, or problems healing during treatment with ELOCON ointment.

The most common side effects of ELOCON ointment include burning, itching, thinning of the skin (atrophy), tingling, stinging, and boils.

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

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 ointment?

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

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

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

What are the ingredients in ELOCON ointment?

Active ingredient: mometasone furoate
Inactive ingredients: hexylene glycol, phosphoric acid, propylene glycol stearate (55% monoester), purified water, white wax, and white petrolatum.

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-ot-XXXXrXXX

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