

## Patient Medication Information

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

<sup>PR</sup>**ELOCOM**<sup>®</sup>

**mometasone furoate cream**  
**mometasone furoate ointment**  
**mometasone furoate lotion**

This Patient Medication Information is written for the person who will be taking **ELOCOM**<sup>®</sup>. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **ELOCOM**, talk to a healthcare professional.

#### **What ELOCOM is used for:**

ELOCOM Cream, Ointment and Lotion is used in adults:

- for the relief of swelling and itching caused by skin conditions like psoriasis and atopic dermatitis (a type of eczema). The lotion may be applied to scalp lesions. ELOCOM can be used for a maximum of:
  - 5 days on the face, scalp, skin-fold areas and groin
  - 3 weeks on the body

#### **How ELOCOM works:**

ELOCOM has anti-inflammatory and vasoconstrictive actions. This constricts blood vessels which helps relieve swelling and itching. The exact mechanism of action is not known.

#### **The ingredients in ELOCOM are:**

Medicinal ingredients: Mometasone furoate

Non-medicinal ingredients:

- Cream: aluminum starch octenylsuccinate, hexylene glycol, hydrogenated soybean lecithin, phosphoric acid, purified water, titanium dioxide, white soft paraffin, white wax
- Ointment: hexylene glycol, phosphoric acid, propylene glycol monostearate, purified water, white soft paraffin, white wax
- Lotion: hydroxypropylcellulose, isopropyl alcohol, phosphoric acid, propylene glycol, purified water, sodium phosphate monobasic

#### **ELOCOM comes in the following dosage forms:**

- ELOCOM Cream 0.1% is supplied in 15 g and 50 g tubes
- ELOCOM Ointment 0.1% is supplied in 50 g tubes
- ELOCOM Lotion 0.1% is supplied in 100 mL plastic bottles

#### **Do not use ELOCOM if:**

- you are allergic to mometasone furoate, other corticosteroids, or to any of the other ingredients of ELOCOM

- you have bacterial, fungal, parasitic, viral skin infection (like herpes simplex, chickenpox)
- you have skin problems related to tuberculosis, syphilis
- you have skin problems from a recent vaccination
- you have acne
- you have rosacea (a facial skin condition)
- you have itchy skin which is not inflamed

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ELOCOM. Talk about any health conditions or problems you may have, including if you:**

- are using or used corticosteroids in the past.
- have any skin problems around a leg ulcer; use of a topical corticosteroid may increase the risk of an allergic reaction or an infection around the ulcer.
- have other inflammatory skin diseases in the leg due to circulation problems.
- are currently treating an infection using an antifungal or antibacterial medicine.
- have kidney or liver problems.
- are 65 years or older.

**Other warnings you should know about:**

#### **High Absorption of ELOCOM:**

- ELOCOM is a topical steroid. If your body absorbs too much topical steroid, it can cause:
  - problems related to a hormone called cortisol, like **Cushing's syndrome**.
  - high sugar levels in your blood (**hyperglycemia**) and urine (**glucosuria**)
- The risks of these problems is higher when ELOCOM is used:
  - for a long time or many times;
  - with an airtight bandage. Do not use ELOCOM with an airtight bandage;
  - on large areas of the body. Your healthcare professional may do tests if ELOCOM is used on large areas to monitor your health.
  - on skin fold areas like the armpit and groin, or delicate skin areas like the face
  - on broken or moist skin.

#### **Eye Problems:**

- Be careful when applying ELOCOM near the eyes.
- ELOCOM is a topical steroid. Topical steroids may cause serious eye problems like **glaucoma**, **cataracts** or **central serious chorioretinopathy (CSCR)**. Talk to your healthcare professional if you have eye problems.

#### **Skin Reactions and Infections:**

- ELOCOM is a topical steroid. Topical steroids may increase the risk of skin infections. The risk is increased if ELOCOM is used on warm, moist skin within skin fold areas like the armpit and groin.
  - Your healthcare professional may stop the doses of ELOCOM and treat the infections as needed.
- ELOCOM contains isopropyl alcohol and may cause some stinging or burning on damaged or sun-burned skin.
- Topical steroids may cause skin stretch marks, skin thinning or discomfort.
  - Be careful when using ELOCOM on your face and skin fold areas like the armpit and groin. These areas are more at risk for skin thinning.
  - Your healthcare professional may stop the doses of ELOCOM and treat as needed.

See the “**Serious side effects and what to do about them**” table, below, for more information on these and other serious side effects.

**Children under 18 years old:**

- ELOCOM is not recommended for use in children under 18 years old.

**Pregnancy and Breastfeeding:**

**Female patients:**

- Talk to your healthcare professional if you are pregnant, breastfeeding, planning to become pregnant or think you are pregnant. There are specific risks you should discuss with your healthcare professional. They will decide if the benefit outweighs the risks.
- If you do breastfeed when using ELOCOM, do not apply it on your breasts, to ensure your baby does not accidentally get it in their mouth.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with ELOCOM:**

- Some medicines used to treat HIV, like ritonavir
- Some medicines used to treat fungal infections, like itraconazole

**How to take ELOCOM:**

- Use ELOCOM only as directed by your health care professional. They will tell you how much to use, how often and how long to use ELOCOM. Check with your healthcare professional if you are not sure.
- Do not use more of it, do not use it more often, and do not use it for a longer period of time than your healthcare professional tells you to.
- Use ELOCOM on the skin and scalp only. Do not use in eyes or any cavity of the body (like the nose, mouth, vagina).
- Do not use ELOCOM with an airtight bandage.

**Usual dose:**

ELOCOM Cream or Ointment

- Apply a thin layer to the affected skin areas once a day.
- Use for a maximum of:
  - 5 days on the face, skin-fold areas and groin.
  - 3 weeks on the body.

Talk to your healthcare professional if your condition gets worse or does not get better within 2 weeks.

ELOCOM Lotion

- Apply a few drops to the affected skin or scalp areas once a day. Massage gently and thoroughly until the lotion disappears.

Use for a maximum of:

- 5 days on the scalp, face, skin-fold areas and groin.
- 3 weeks on the body.

Talk to your healthcare professional if your condition gets worse or does not get better within 2 weeks.

### Overdose:

If you think you, or a person you are caring for, have taken too much ELOCOM, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

### Missed Dose:

If you missed a dose of ELOCOM, apply it as soon as you remember. If it is close to the time for your next dose, skip the missed dose and continue with your next scheduled dose. Go back to the regular dosing schedule. Do not apply extra ELOCOM to make up for missed doses.

### Possible side effects from using ELOCOM:

These are not all the possible side effects you may have when taking ELOCOM. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- skin problems such as:
  - acne, pimples
  - burning, tingling, stinging
  - numbness
  - inflammation of hair follicles (reddish or purple bumps)
  - softening and thinning of the skin
  - strong itching
  - dry skin
  - abnormal redness
  - skin swelling
  - larger lesion size
  - heat rash
- nausea
- aggravation of the disease
- dermatitis
- infections or signs of infection, irritation
- stretch marks
- unwanted hair
- lightening of skin color
- vaginal discharge

ELOCOM can cause abnormal blood and urine test results. Your healthcare professional will decide when to do the tests. These will tell your healthcare professional how ELOCOM is affecting your health.

### Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Uncommon			
Allergic contact dermatitis: skin rash or irritation including itching		√	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
and redness, peeling, burning, or stinging			
<b>Allergic reaction:</b> chills, fever, muscle aches or pains or other flu-like symptoms occurring with or before a skin rash			√
<b>Skin reaction and infections:</b> skin thinning, pain, tenderness, swelling, redness of the skin		√	
<b>Rare</b>			
<b>Cushing's Syndrome:</b> weight gain, moon face / rounding of the face, obesity, fragile skin that bruises easily, slow healing of cuts, severe fatigue, muscle weakness, headache, bone loss leading to fractures over time			√
<b>Unknown</b>			
<b>Eye problems (Glaucoma, Cataracts, or Central Cerous Chorioretinopathy (CSCR)):</b> blurred vision, increased pressure in your eyes, eye pain, distorted vision, clouding of the lens in the eye, redness in the eye		√	
<b>Glucosuria (sugar in urine):</b> excessive or sweet-smelling urine		√	
<b>Hyperglycemia</b> (increased blood sugar): frequent urination, thirst, hunger, , dry skin, headache, blurred vision and fatigue		√	
<b>Hypertension</b> (high blood pressure): headaches, vision disorders, nausea and vomiting		√	
<b>Osteoporosis</b> (thin, fragile bones): weakening of the bones potentially leading to an increased risk of bone fracture		√	
<b>Steroid Withdrawal Syndrome:</b> weight loss, fatigue, nausea, diarrhea and abdominal pain		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting ([canada.ca/drug-device-reporting](https://canada.ca/drug-device-reporting)) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

- ELOCOM Cream and ELOCOM Ointment: Store between 15° and 30°C.
- ELOCOM Lotion: Store between 15° and 25°C.
- Do NOT use if past expiry date on the label.
- Keep out of reach and sight of children.

### If you want more information about ELOCOM:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.organon.ca](https://www.organon.ca), or by calling 1-844-820-5468.

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