

PART III: CONSUMER INFORMATION



**Mometasone Furoate Cream, BP
Mometasone Furoate Ointment, Organon Standard
Mometasone Furoate Lotion**

This leaflet is part III of a three-part “Product Monograph” published when ELOCOM® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ELOCOM®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

In adult, ELOCOM® Cream, Ointment and Lotion:

- are used 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.
- can be used for a maximum of:
 - 5 days on the face, scalp, skin-fold areas and groin
 - 3 weeks on the body

What it does:

ELOCOM®, has anti-inflammatory and vasoconstrictive actions (makes blood vessels constrict) to help relieve swelling and itching. The exact mechanism of action is not known.

When it should not be used:

Do not use ELOCOM® Cream, Ointment or Lotion if you:

- are allergic to mometasone furoate, other corticosteroids, or to any of the other ingredients of ELOCOM®
- have bacterial, fungal, parasitic, viral skin infection (e.g. herpes simplex, chickenpox), tuberculous or syphilis skin lesions, or skin reaction following a recent vaccination
- have acne
- have rosacea (a facial skin condition where the nose, cheeks, chin, forehead or entire face are unusually red, with or without tiny visible blood vessels, bumps (papules) or pus-filled bumps (pustules))
- have itchy skin which is not inflamed

Do not apply ELOCOM® in the eyes.

What the medicinal ingredient is:

Mometasone furoate

What the important nonmedicinal ingredients are:

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

What dosage forms it comes in:

- 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 75 mL plastic bottles

WARNINGS AND PRECAUTIONS

Apply just enough ELOCOM® to cover the areas. ELOCOM® can get into the blood and cause side effects.

Always follow your doctor’s instructions.

ELOCOM® is **NOT** recommended for use with airtight bandage.

ELOCOM® is more likely to cause side effects when used:

- over large areas
- on sensitive areas such as the face, scalp, skin fold areas like the armpit and groin
- on broken skin
- for a long time

Inform any doctor you consult that you are using or have previously used corticosteroids.

Before using ELOCOM®, talk to your doctor or pharmacist if:

- you have any skin disease around a leg ulcer; use of a topical corticosteroid may increase the risk of an allergic reaction or an infection around the ulcer.
- you are currently treating an infection using an antifungal or antibacterial agent.
- you have other inflammatory skin diseases in the leg as a result of impaired circulation (such as stasis dermatitis).
- you are pregnant or planning to become pregnant.
- you are breastfeeding. It is not known if ELOCOM® will appear in breast milk. You should only use ELOCOM® while breastfeeding if you and your doctor decide if the benefits to the mother outweigh the risks to the baby. If you do breastfeed when using ELOCOM®, do not apply it on your breasts to ensure the infant does not accidentally get it in their mouth.
- you have problems with your kidney and liver. You may need to use a smaller amount of ELOCOM® or use it less often.

IMPORTANT: PLEASE READ

While using ELOCOM[®], talk to your doctor or pharmacist if:

- you develop any skin infection
- you have an allergic reaction
- you develop significant skin irritation
- you experience skin thinning or softening
- your condition worsens or does not improve

Care should be taken when applying ELOCOM[®] to the face or in skin-fold areas, such as the groin and the armpit since these areas are more prone to skin thinning.

Use with caution when applying ELOCOM[®] near the eyes.

Children absorb larger amounts of topical corticosteroids and therefore, may be more likely to develop side effects. **ELOCOM[®] is not recommended for use in children under 18 years of age.**

Do NOT cover the affected skin or scalp areas with airtight bandages.

INTERACTIONS WITH THIS MEDICATION

It is **NOT** known whether ELOCOM[®] interacts with other medication. Some medicines may affect how ELOCOM[®] works and may make it more likely that you will have side effects. Some of these medicines may include:

- Ritonavir (for HIV).
- Itraconazole (for fungal infections).

Tell your doctor or pharmacist about all your other medications, including medicines that you bought without a prescription and natural health products.

PROPER USE OF THIS MEDICATION

Use the minimum quantity of ELOCOM[®] for the shortest amount of time necessary to achieve the desired results. This is especially important if you are 65 years or older or have liver or kidney disease.

ELOCOM[®] is for use on the skin and scalp only. It is **NOT** for use in the eyes or other mucous membranes.

Usual Adult Dose:

ELOCOM[®] Cream or Ointment

Apply a thin film to the affected skin areas once a day or as directed by your doctor.

Use for a maximum of:

- 5 days on the face, skin-fold areas and groin.
- 3 weeks on the body. If your condition worsens or no improvement is seen within 2 weeks, contact your doctor.

ELOCOM[®] Lotion

Apply a few drops to the affected skin areas (which may include scalp sites) once a day, or as directed by your doctor. Massage gently and thoroughly until the medication disappears.

Use for a maximum of:

- 5 days on the scalp, face, skin-fold areas and groin.
- 3 weeks on the body. If your condition worsens or no improvement is seen within 2 weeks, contact your doctor.

Use ELOCOM[®] only as directed by your health care provider. **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 health care provider recommended.** Using too much ELOCOM[®] may increase your chances of unwanted and sometimes dangerous side effects.

This medication has been prescribed specifically for you. Do NOT give it to anyone else. It may harm them, even if their symptoms seem to be similar to yours.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you forget to use ELOCOM[®], apply it as soon as you remember. If it is close to the time scheduled to apply your next dose, wait and apply your next scheduled dose and then continue as before. Do not apply extra ELOCOM[®] to make up for missed doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- your condition worsens or does not improve
- skin sensations such as:
 - burning, tingling, or stinging
 - strong itching sensation
 - softening and thinning of the skin
 - inflammation of hair follicles
 - acne-like reactions

Very rarely the following may occur:

- aggravation of the disease
- dry skin, abnormal redness, appearance of boils, aggravated allergy, dermatitis (swelling of the skin), increased lesion size
- nausea

Additionally, the following side effects have been found to occur with the use of other topical corticosteroids:

- infection or signs of infection, irritation
- unwanted hair, lightening of skin color
- dermatitis (swelling of the skin) near or around the mouth, allergic contact dermatitis
- stretch marks
- heat rash

ELOCOM[®] can cause abnormal blood and urine test results. Your doctor will decide when to perform tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Allergic reaction: chills, fever, muscle aches or pains or other flu-like symptoms occurring with or before a skin rash			✓
	Cushing's Syndrome: weight gain, moon face / rounding of the face and obesity			✓
Unknown	Steroid Withdrawal Syndrome: weight loss, fatigue, nausea, diarrhea and abdominal pain		✓	
	Hyperglycemia (increased blood sugar): frequent urination, thirst and hunger		✓	
	Glucosuria (sugar in urine): excessive or sweet smelling urine		✓	
	Hypertension (high blood pressure): headaches, vision disorders, nausea and vomiting		✓	
	Osteoporosis: weakening of the bones potentially leading to an increased risk of bone fracture		✓	
	Glaucoma, Cataracts, or central serous chorioretinopathy (CSCR): blurred vision, increased pressure in your eyes, eye pain, distorted vision		✓	

This is not a complete list of side effects. For any unexpected effects while taking ELOCOM[®] cream, ointment or lotion contact your doctor or pharmacist.

HOW TO STORE IT

Store between 15° and 30°C

Do **NOT** use if past expiry date on the label.

Keep out of reach of children

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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.

MORE INFORMATION

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 this Consumer Information by visiting the [Health Canada website](#) or Organon Canada website www.organon.ca or by calling Organon Canada at 1-844-820-5468.

This leaflet was prepared by Organon Canada Inc.

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