

**PART III: CONSUMER INFORMATION**

**ELOCOM**

- Mometasone furoate Cream, 0.1%**
- Mometasone Furoate Ointment, 0.1%**
- Mometasone Furoate Lotion, 0.1%**

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:**

ELOCOM (mometasone furoate) Cream, Ointment and Lotion 0.1% provide:

- the relief of swelling and itching caused by skin conditions like psoriasis and atopic dermatitis. The lotion may be applied to scalp lesions.

**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 0.1%

- if you are allergic to mometasone furoate, to other corticosteroids or to any of the ingredients included in these products. (*See section, What the important nonmedicinal ingredients are*).
- if you presently have a skin infection of fungal, bacterial or viral origin (i.e. herpes simplex, chicken pox and vaccinia).

**What the medicinal ingredient is:**

Mometasone furoate

**What the important nonmedicinal ingredients are:**

Cream:

- aluminum starch octenylsuccinate
- cetareth-20
- hexylene glycol
- phosphoric acid

- propylene glycol monostearate
- purified water
- stearyl alcohol
- titanium dioxide
- white petrolatum
- white wax

Ointment:

- hexylene glycol
- phosphoric acid
- propylene glycol monostearate
- purified water
- white petrolatum
- 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 15 g; and 50 g tubes
- ELOCOM Lotion 0.1% is supplied in 30 mL and 75 mL plastic bottles

**WARNINGS AND PRECAUTIONS**

**BEFORE you use ELOCOM talk to your doctor or pharmacist if:**

- you have had any side effects caused by previous use of other topical corticosteroids (anti-inflammatory medicine to apply to the skin). Side effects may include:
  - Allergic reaction
  - Irritation
  - Adrenal suppression (characterized by darkening of the skin, fatigue, low blood pressure, diarrhea, and digestive disturbance).
- you are currently treating an infection using an antifungal or antibacterial agent.
- You are pregnant or nursing
- You have used steroid hormone medication in the past
- You have poor circulation due to stasis dermatitis (an inflammation of the skin) or other skin diseases

For external use on skin or scalp only.

Do not use in or nears the eyes.

**INTERACTIONS WITH THIS MEDICATION**

It is **NOT** known whether ELOCOM interacts with other medication.

**PROPER USE OF THIS MEDICATION**

**Usual dose:**

ELOCOM Cream/Ointment: Apply a thin film to the affected skin areas once daily or as directed by your doctor; massage gently and thoroughly.

ELOCOM Lotion: Apply a few drops of the lotion to the affected skin areas (which may include scalp sites) once daily, or as directed by your doctor; massage gently and carefully until medication disappears.

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

Use ELOCOM only as directed by your health care provider. **Do NOT use more of it, do NOT take it more often and do NOT take 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:**

Symptoms: fatigue, weakness, decreased appetite, constipation, nausea, vomiting, diarrhea, abdominal pain, skin colour darkening (especially on scars, elbows, knees, knuckles, toes, lips, and mucous membranes).

Treatment: **In case of overdosage, contact your doctor or poison control center immediately.**

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Along with desirable effects, Elocom may cause undesirable effects.

Side effects that may occur with the use of this medication include: skin sensation such as burning or tingling, or stinging strong itching sensation and signs of skin atrophy (thinning of the skin), as well as inflammation of hair follicles, and 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 and 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 as well as kidney suppression, demonstrated by decreased urine, increased blood pressure, heart palpitations, shortness of breath, itching, nausea, loss of appetite, upset stomach, and joint inflammation.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Un-common	Allergic reaction to the medication (chills, fever, muscle aches or pains or other flu-like symptoms occurring with or before a skin rash)			✓
Rare	Symptoms associated with Kidney suppression (see symptoms listed above)			✓
Rare	Symptoms associated with Adrenal suppression (see symptoms listed in <i>WARNINGS and PRECAUTIONS</i> section)			✓

*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 SUSPECTED SIDE EFFECTS

**To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:**

**toll-free telephone: 866-234-2345**

**toll-free fax 866-678-6789**

**By email: [cadtmp@hc-sc.gc.ca](mailto:cadtmp@hc-sc.gc.ca)**

**By regular mail:**

**National AR Centre**

**Marketed Health Products Safety and Effectiveness**

**Information Division**

**Marketed Health Products Directorate**

**Tunney's Pasture, AL 0701C**

**Ottawa ON K1A 0K9**

***NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.***

## MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Merck Canada Inc. at: 1-800-463-5442

This leaflet was prepared by Merck Canada Inc.

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