

## CONSUMER INFORMATION

# ELOCOM™

## BP Mometasone Furoate, Merck Standard

### Mometasone Furoate Lotion

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, Lotion:

- is 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 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), tuberculosis 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:

Lotion:

- hydroxypropylcellulose
- isopropyl alcohol
- phosphoric acid
- propylene glycol
- purified water
- sodium phosphate monobasic

##### What dosage forms it comes in:

- ELOCOM Lotion 0.1% is supplied in 30 mL and 75 mL plastic bottles

Not all pack sizes may be marketed.

#### 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.

##### 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 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	
Un-common	Allergic reaction: chills, fever, muscle aches or pains or other flu-like symptoms occurring with or before a skin rash			✓
Rare	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 lotion contact your doctor or pharmacist.

#### HOW TO STORE IT

Store between 2° and 30°C

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

Keep out of reach of children

#### MORE INFORMATION

##### Marketing Authorization Holder:

Merck Canada Inc. 16750 Transcanadienne  
Kirkland, Quebec, Canada  
H9H 4M7

##### Manufacturer and batch releaser:

Famar Montréal Inc.  
3535 Route Trans Canada Highway  
Pointe-Claire, Quebec, H9R 1B4,  
Canada

##### Reporting Side Effects

NOTE: Contact your health professional if you need information about how to manage your side effects.

##### 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 Merck Canada website www.merck.ca.

This leaflet was prepared by Merck Canada Inc.

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#### (THIS IS A MEDICATION)

- Medication is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medication out of reach of children  
Council of Arab Health Ministers  
Union of Arab Pharmacists

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