

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS
(PREPARATIONS) - 1986**

This medicine can be sold under doctor's prescription only

ELOCOM[®] LOTION

Mometasone furoate 0.1%

Each gram contains 1 mg of mometasone furoate.

For a list of inactive ingredients see section 6 "FURTHER INFORMATION". See also section 2.5 "Important information about some of the ingredients of **ELOCOM LOTION**".

Read all of this leaflet carefully before you start using this medicine.

- This leaflet contains concise information about **ELOCOM LOTION**. If you have any further questions, refer to the doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their ailment seems similar to yours.

1. WHAT IS ELOCOM LOTION INTENDED FOR?

ELOCOM LOTION is used to reduce inflammation and itchiness caused by certain corticosteroid-responsive skin and scalp problems, such as psoriasis or atopic dermatitis.

Therapeutic group: **ELOCOM LOTION** belongs to a group of medicines called topical corticosteroids. It is classified as a "potent corticosteroid". These medicines are put on the surface of the skin to reduce the redness and itchiness caused by certain skin problems.

What is psoriasis?

Psoriasis is a skin disease in which itchy, scaly, pink patches develop on the elbows, knees, scalp and other parts of the body.

What is dermatitis?

Dermatitis is a condition brought on by the skin reacting to outside agents e.g. detergents, causing the skin to become red and itchy.

2. BEFORE USING ELOCOM LOTION

2.1 Do not use ELOCOM LOTION if:

- You are allergic (hypersensitive) to mometasone furoate or any of the other ingredients of **ELOCOM LOTION** (refer to sections 2.5 and 6), or to other similar medicines
- You have skin or scalp problems as it could make them worse, chickenpox, shingles, warts, other skin infections, ulcerated skin, wounds, skin atrophy (thinning of the skin)

Ask your doctor or pharmacist if you are not sure.

2.2 Special warnings regarding use of ELOCOM LOTION

Contact your doctor if your psoriasis gets worse or you get raised bumps filled with pus under your skin.

Contact your doctor immediately if you experience blurred vision or other visual disturbances.

If your skin or scalp becomes irritated or sensitive after using **ELOCOM LOTION**, you should stop using it and tell your doctor.

If you think that you have developed an infection on your scalp whilst using **ELOCOM LOTION**, you should tell your doctor.

Side effects that may happen with inhaled or oral corticosteroids may also occur with corticosteroids used on the skin, especially in infants and children.

If you use more than the correct amount of lotion and/or use it for longer than is recommended, it can affect the levels of certain hormones in the body, particularly in infants and children.

In adults the changes in hormone levels may lead rarely to puffiness or rounding of the face, weakness, tiredness, and dizziness when standing or sitting down.

Do not smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

If there is a worsening of your condition during use consult your doctor – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment.

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the lotion without consulting your doctor unless your doctor has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

Children and adolescents

The use of **ELOCOM LOTION** in children under the age of 2 years is not recommended.

If more than the correct amount of lotion is used and/or it is used for longer than is recommended, or on large areas of the body, it can affect the child's hormones. This may lead to:

- Delayed growth and development
- Puffiness or rounding of the face

2.3 Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, you should tell the doctor or pharmacist.

2.4 Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

2.5 Important information about some of the ingredients of ELOCOM LOTION

ELOCOM LOTION contains propylene glycol, which can cause skin irritation.

3. HOW SHOULD YOU USE ELOCOM LOTION?

Always use **ELOCOM LOTION** exactly as instructed by the doctor. You should check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen.

The dosage and treatment regimen will be determined by the doctor only.

Usually, the acceptable dosage is:

A few drops of **ELOCOM LOTION** should be gently massaged into the affected area of the skin or scalp, once a day. Massage gently and thoroughly until absorption of the medication. Apply with the aid of your finger and then wash your finger thoroughly.

ELOCOM LOTION is not intended for use in children under the age of 2 years.

Do not exceed the recommended dose.

Do not swallow, for external use only.

You should always follow these instructions when using ELOCOM LOTION:

Do not use **ELOCOM LOTION** on your face or in children for more than 5 days.

Do not put **ELOCOM LOTION** under your child's diaper, as this makes it easier for the active drug to pass through the skin and possibly cause some unwanted effects.

You should check with your doctor before covering the treated areas with a bandage or plaster. Treated areas on the face or in children should not be covered with a bandage or plaster.

You should not use a large amount of **ELOCOM LOTION** on large areas of the body for a long time (for example every day for many weeks or months).

Do not use in or around the eyes, including eye-lids, because of the very rare risk of glaucoma or cataract. Avoid contact with mucous membranes (e.g. in mouth and nose). In case of contact wash thoroughly.

If you have used more ELOCOM LOTION than you should

If you (or somebody else) accidentally swallow **ELOCOM LOTION**, it should not produce any problems. However, if you are worried, you should see your doctor.

If you use **ELOCOM LOTION** more often than you should, or on large areas of the body, it can affect some of your hormone's levels. In children, this may affect their growth and development.

If you have not used **ELOCOM LOTION** as you were told to do and have used it too often and/or for a long time, you should tell a doctor.

If you have forgotten to use ELOCOM LOTION

It is important to use **ELOCOM LOTION** as the doctor has prescribed. If you forget to use **ELOCOM LOTION** at the right time, use it as soon as you remember, then carry on as before.

If you stop using ELOCOM LOTION

If you have been using **ELOCOM LOTION** for a long time and your skin or scalp problem seems to have got better, you should not suddenly stop using **ELOCOM LOTION**. If you do, you may find that your skin and scalp becomes red and you may notice stinging and burning. To avoid this, you should speak to your doctor as he will gradually reduce how often you need to use **ELOCOM LOTION** until you stop treatment altogether.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have further questions on the use of the medicine, consult with a doctor or a pharmacist.

4. SIDE EFFECTS

As with any medicine, **ELOCOM LOTION** may cause side effects in some users.

Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

A few people may find that they suffer from some of the following side effects after using **ELOCOM LOTION**:

- allergic skin reactions
- bacterial and secondary skin infections
- acne
- inflammation and/or infection of the hair follicles
- thinning of the skin
- red marks with associated prickly heat
- loss of skin colour
- burning
- stinging
- itching
- tingling

- excessive hair growth
- softening of the skin and stretch marks
- blurred vision.

Steroid withdrawal reaction:

If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

Other side effects that may occur with topical corticosteroids are dry skin, skin irritation, dermatitis, dermatitis around the mouth, and small dilated blood vessels.

If a side effect appears, if any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by using the link "Reporting side effects due to medicinal treatment" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link: <https://sideeffects.health.gov.il/>

5. HOW TO STORE ELOCOM LOTION?

- Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use **ELOCOM LOTION** after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated month.
- Store not above 25°C.
- After first opening, can be used for 3 months.
- Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

6.1 What ELOCOM LOTION contains

In addition to the active ingredient, **ELOCOM LOTION** also contains:

Isopropyl alcohol, propylene glycol, sodium dihydrogen phosphate dihydrate, hydroxypropyl cellulose, phosphoric acid, purified water.

6.2 What ELOCOM LOTION looks like and contents of the pack

ELOCOM LOTION is a colorless to off-white lotion. Available in bottles containing 20 ml.

6.3 Manufacturer

Organon LLC, NJ USA

6.4 License holder and address

Organon Pharma Israel Ltd., 1 Atir Yeda, Kfar Saba

Revised in June 2022 according to MOH guidelines.

Drug registration no. listed in the official registry of the Ministry of Health:

137.48.28715