

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

This medicine can be sold under doctor's prescription only

ELOCOM[®] CREAM

Mometasone furoate 0.1%

Each gram of cream contains:
1 mg of mometasone furoate

ELOCOM[®] OINTMENT

Mometasone furoate 0.1%

Each gram of ointment 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 OINTMENT**".

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

- This leaflet contains summary information about **ELOCOM**. 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 ELOCOM IS INTENDED FOR?

ELOCOM is used for the relief of the inflammatory and pruritic manifestations of corticosteroid - responsive dermatoses such as psoriasis and atopic dermatitis

Therapeutic group: **ELOCOM CREAM** and **ELOCOM OINTMENT** belong 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 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

2.1 Do not use ELOCOM if:

- you are allergic (hypersensitive) to mometasone furoate or any of the other ingredients of **ELOCOM** (refer to sections 2.5 and 6), or to other similar medicines.
- you have any other skin problems as it could make them worse, especially: rosacea (a skin condition affecting the face); acne; skin atrophy (thinning of the skin); dermatitis around the mouth; genital itching; nappy rash; cold sores; chickenpox; shingles; warts; ulcerated skin; wounds; other skin infections.

Ask your doctor or pharmacist if you are not sure.

2.2 Special warnings regarding use of ELOCOM

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

If you think that you have developed an infection on your skin while using **ELOCOM**, 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 **ELOCOM** 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 **ELOCOM** 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

As the safety and efficacy of **ELOCOM** in pediatric patients below 2 years of age have not been established, its use in this age group is not recommended. Special caution is required when using this medicine in children and adolescents. Use in these age groups must be carried out under medical surveillance.

If more than the correct amount of **ELOCOM** is used and/or it is used for longer than is recommended, 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

You should tell your doctor if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, before you start using **ELOCOM**.

2.5 Important information about some of the ingredients of ELOCOM OINTMENT

ELOCOM OINTMENT contains propylene glycol stearate, which can cause skin irritation.

3. HOW SHOULD YOU USE ELOCOM?

Always use **ELOCOM** 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 thin layer of **ELOCOM** Cream or Ointment should be gently rubbed into the affected area of skin, once a day. Massage gently and thoroughly until the medication disappears. Apply with the aid of your finger and then wash your finger thoroughly.

Do not use the cream or ointment on your face for more than 5 days

Do not exceed the recommended dose.

Do not swallow, for external use only.

You should always follow these instructions when using ELOCOM:

Do not put **ELOCOM** 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** 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 than you should

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

If you use **ELOCOM** 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** as you were told to do and have used it too often and/or for a long time, you should tell the doctor.

If you have forgotten to use ELOCOM

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

If you stop using ELOCOM

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

- 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?

- Avoid Poisoning! This medicine, and any other medicine, 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** 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.
- **ELOCOM CREAM** - after first opening, can be used for 3 months.
- **ELOCOM OINTMENT** - after first opening, can be used for 1 month.
- Medicines should not be disposed via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

6.1 What ELOCOM CREAM contains

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

White soft paraffin; hexylene glycol; aluminium starch octenylsuccinate; white wax; purified water; hydrogenated soybean lecithin; titanium dioxide; phosphoric acid.

6.2 What ELOCOM OINTMENT contains

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

White soft paraffin; hexylene glycol; white wax; purified water; propylene glycol stearate; phosphoric acid.

6.3 What ELOCOM looks like and contents of the pack

ELOCOM CREAM is a white to off-white smooth homogeneous cream. Available in a tube containing 15 grams.

ELOCOM OINTMENT is a white to off-white opaque ointment. Available in a tube containing 15 grams.

6.4 Manufacturer

Organon LLC, NJ USA

6.5 License holder and address

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

Revised in November 2023 according to MOH guidelines.

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

ELOCOM CREAM: 060.05.26514

ELOCOM OINTMENT: 060.06.26513