

PACKAGE LEAFLET: INFORMATION FOR THE USER

ELOCON® 0.1% w/w Ointment

mometasone furoate

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What ELOCON is and what it is used for
2. Before you use ELOCON
3. How to use ELOCON
4. Possible side effects
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6. Further information

1. WHAT ELOCON IS AND WHAT IT IS USED FOR

ELOCON Ointment is one of 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.

In adults and children, ELOCON Ointment is used to reduce redness and itchiness caused by certain skin problems called psoriasis or dermatitis.

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

Do not use ELOCON

- if you are allergic (hypersensitive) to mometasone furoate, any of the other ingredients of ELOCON or to other similar medicines.
- on 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, ulcerated skin, wounds or other skin infections and widespread plaque psoriasis. Ask your doctor or pharmacist if you are not sure.
- to treat skin problems in children under one year of age, including nappy rash and dermatitis.

Take special care with ELOCON

- if your skin becomes irritated or sensitive after using ELOCON, you should stop using it and tell your doctor.
- if you think that you have developed a skin infection whilst using ELOCON, you should tell your doctor as he may need to give you another type of medicine to use.

Side effects that may happen with oral or injectable corticosteroids, including adrenal insufficiency, may also occur with corticosteroids used on the skin, especially in infants and children. See section 4.

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

Pregnancy and breast-feeding

You should tell your doctor if you are pregnant or breast-feeding, before you start using ELOCON.

3. HOW TO USE ELOCON

Always use ELOCON exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Usually for adults and children, a thin layer of ELOCON Ointment should be gently rubbed into the affected area of skin once a day.

You should always follow these instructions when using ELOCON:

- Do not use the ointment on your face for more than 5 days.
- Do not apply the ointment to children, on any part of their body, for more than 5 days.
- Do not put the ointment under your child's nappy, as this makes it easier for the active drug to pass through the skin and possibly cause some unwanted effects.
- You should not use a large amount of ointment 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 your eyes, including eye-lids.

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 Elocon may increase your chances of side effects.

If you use more ELOCON than you should

If you (or somebody else) accidentally swallows the ointment, it should not produce any problems. However, if you are worried, you should see your doctor.

If you use the ointment more often than you should, or on large areas of the body, it can affect some of your hormones. In children, this may affect their growth and development.

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

If you forget to use ELOCON

If you forget to use your ointment at the right time, use it as soon as you remember, then carry on as before.

If you stop using ELOCON

If you have been using ELOCON for a long time and your skin problem seems to have got better, you should not suddenly stop using the ointment. 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 as he will gradually reduce how often you need to use the ointment until you stop treatment altogether.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ELOCON can cause side effects, although not everybody gets them.

A few people may find that they suffer from some of the following side effects after using ELOCON: burning, stinging, itching, tingling, inflammation and/or infection of the hair follicles, allergic skin reactions, loss of skin colour, excessive hair growth, thinning of the skin, red marks with associated prickly heat, acne, bacterial and secondary skin infections, softening of the skin, stretch marks and blurred vision.

Side effects that may happen with oral or injectable corticosteroids, including adrenal insufficiency, may also occur with corticosteroids used on the skin, especially in infants and children. Adrenal insufficiency is a condition in which the adrenal glands do not make enough steroid hormones. Symptoms of adrenal insufficiency can include: tiredness, weakness, nausea and vomiting and low blood pressure. Tell your doctor if you think you have these symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Ireland: HPRA Pharmacovigilance Website: www.hpra.ie

Malta: ADR Reporting at: www.medicinesauthority.gov.mt/adrportal

5. HOW TO STORE ELOCON

The ointment should not be stored above 25°C. Keep out of the reach of children. Do not use ELOCON after the expiry date which is stamped on the pack.

6. FURTHER INFORMATION

What ELOCON contains

- The active substance is mometasone furoate 0.1% w/w

- The other ingredients are hexylene glycol; purified water; phosphoric acid; propylene glycol stearate (E477); white beeswax; white petrolatum. This medicine contains 20 mg propylene glycol stearate (E477) in each gram of the ointment. This is equivalent to 600.0 mg propylene glycol stearate per unit (30 g tube).

What ELOCON looks like and contents of the pack

The ointment is available in a tube containing 5, 15, 30, 45 and 100 g. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The holder of the Marketing Authorisation is:

Ireland:

Organon Pharma (Ireland) Limited, 2 Dublin Landings, North Wall Quay - North Dock, Dublin, D01V4A3, Ireland

Malta:

N.V. Organon, Kloosterstraat 6, NL-5349 AB Oss, The Netherlands

The manufacturer is:

Schering-Plough Labo NV, Heist-op-den Berg, Belgium.

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