

Package leaflet: Information for the user

Elocon® 0.1% w/w Scalp Lotion

Mometasone furoate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet:

1. What Elocon is and what it is used for
2. What you need to know before you use Elocon
3. How to use Elocon
4. Possible side effects
5. How to store Elocon
6. Contents of the pack and other information

1. What Elocon is and what it is used for

Elocon Scalp Lotion is one of a group of medicines called topical corticosteroids. These medicines are put on the surface of the skin to reduce the redness and itchiness caused by certain skin problems. Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Elocon is classed as a strong corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

In adults and children, Elocon Scalp Lotion is used to reduce redness and itchiness caused by certain conditions affecting the scalp, 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. What you need to know before you use Elocon

Do not use Elocon if you have any of the following:

- Allergies (hypersensitivity) to mometasone furoate, or any of the other ingredients of this medicine (listed in section 6) or to other similar medicines

- 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.

Warnings and precautions

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

If you think that you have developed an infection on your scalp whilst using Elocon, 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 prescriber – 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 prescriber unless your prescriber 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

Elocon is not recommended for children under the age of 2.

If more than the correct amount of lotion 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

Other medicines and Elocon Scalp Lotion

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

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.

Elocon Scalp Lotion contains propylene glycolstearate, which can cause skin irritation.

3. How to use Elocon

Always use Elocon exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Use in Children

- Elocon is not recommended for children under the age of 2.
- Do not use the lotion on your child's scalp for more than 5 days.
- Treated areas in children should not be covered with a bandage or plaster.
- If you use the lotion on your child more often than you should, or on large areas of the body, it can affect some of their hormones, and this may affect their growth and development.

Before using Elocon

You should always follow these instructions when using Elocon:

- This medicine should only be used on the scalp. Do not use it on any other part of your body.
- You should check with your doctor before covering the treated areas with a bandage or plaster. Treated areas on the face should not be covered with a bandage or plaster.
- You should not use a large amount of 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.

How to use Elocon

- Usually for adults and children, a few drops of ELOCON Scalp Lotion should be applied to the affected area of the scalp once a day and gently massage until the lotion disappears.
- The hair can be wet or dry when applying the lotion to the scalp.

If you use more Elocon than you should

- If you (or somebody else) accidentally swallows the lotion, it should not produce any problems. However, if you are worried, you should see your doctor.
- If you use the lotion 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 lotion 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 lotion 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 the lotion for a long time and your scalp problem seems to have got better, you should not suddenly stop using the lotion. If you do, you may find that your scalp becomes

red and you may notice stinging and burning. To avoid this, you should speak to your doctor who will gradually reduce how often you need to use the lotion 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:

- Allergic skin reactions
- Bacterial and secondary skin infections
- Acne
- Inflammation and/or infection of the hair follicles
- Thinning of the skin
- Red marks with associate 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 over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after 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.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Elocon

- The lotion should be stored below 25 °C.
- Keep this medicine out of the sight and reach of children.
- Do not use Elocon after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Elocon contains

- The active substance is mometasone furoate, each gram contains 1 mg of mometasone furoate.
- The other ingredients are isopropyl alcohol, propylene glycol, hydroxypropyl cellulose, sodium dihydrogen phosphate dihydrate, phosphoric acid, purified water.

What Elocon looks like and contents of the pack

The lotion is available in bottles containing 30 ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Organon Pharma (UK) Limited, The Hewett Building, 14 Hewett Street, London EC2A 3NP, UK

Manufacturer:

Organon Heist bv, Industriepark 30, 2220 Heist-op-den-Berg, Belgium

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