

PACKAGE LEAFLET: INFORMATION FOR THE USER

Elocon® 0.1% w/w Scalp Lotion

Cutaneous Solution

0.1% w/w mometasone furoate (equivalent to 1.0 mg/g)

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 get 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
5. How to store Elocon
6. Further information

1. WHAT ELOCON IS AND WHAT IT IS USED FOR

Elocon Scalp Lotion 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 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. 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 scalp problems as it could make them worse especially chickenpox, shingles, ulcerated skin, wounds, skin atrophy (thinning of the skin) or other infections of the scalp. Ask your doctor or pharmacist if you are not sure.
- to treat scalp infections in children under one year of age, including dermatitis.

Take special care with Elocon

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

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.

Elocon Scalp Lotion contains propylene glycol (E1520).

Propylene glycol may cause skin irritation.

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 few drops of Elocon Scalp Lotion should be gently massaged into the affected area of the scalp once a day.

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.
- Do not use the lotion on your child's scalp for more than 5 days.
- 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 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 swallow 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 as he 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: 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 via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE ELOCON

The lotion should not be stored above 25°C.

Keep out of the reach and sight of children.

Do not use Elocon after the expiry date “use by” which is stamped on the bottle and carton. This refers to the last date of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Elocon contains

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

- The other ingredients are isopropyl alcohol, propylene glycol (E1520), hydroxypropyl cellulose, sodium dihydrogen phosphate dihydrate, phosphoric acid, purified water. This medicine contains 300 mg propylene glycol (E1520) in each milliliter of the lotion. This is equivalent to 9.0 g of propylene glycol per unit (30 ml bottle).

What Elocon looks like and contents of the pack

The lotion is available in bottles containing 30 ml.

Marketing Authorisation Holder and Manufacturer

The holder of the Marketing Authorisation is:

Organon Pharma (Ireland) Limited
2 Dublin Landings
North Wall Quay - North Dock
Dublin, D01 V4A3
Ireland.

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The manufacturer is:

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

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