

PACKAGE LEAFLET: INFORMATION FOR THE USER

Elocon ® Cream

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
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1. WHAT ELOCON IS AND WHAT IT IS USED FOR

ELOCON Cream 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 Cream 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 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
 - warts
 - ulcerated skin
 - wounds
 - other skin infections

Ask your doctor or pharmacist if you are not sure.

Take special care with ELOCON

— if your skin becomes irritated or sensitive after using ELOCON, you should stop using it and tell your doctor

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

Usually for adults and children, a thin layer of ELOCON Cream 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 cream on your face for more than 5 days.
- Do not apply the cream to children, on any part of their body, for more than 5 days.
- Do not put the cream 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 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 cream 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.

If you use more ELOCON than you should

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

If you use the cream 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 cream 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 cream 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 cream. 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 cream 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 associated prickly heat
- loss of skin colour
- burning
- stinging
- itching

- tingling
- excessive hair growth
- softening of the skin and stretch marks

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 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.

5. HOW TO STORE ELOCON

The cream should be stored below 25°C. Store in the original package.

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; titanium dioxide; aluminium starch octenylsuccinate; white wax; white soft paraffin and hydrogenated soybean lecithin.

What ELOCON looks like and contents of the pack

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

Marketing Authorisation Holder and Manufacturer

The holder of the Marketing Authorisation is:

Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Hertfordshire, EN11 9BU, UK.

The manufacturer is:

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

This leaflet was last updated in January 2013