

## **Package leaflet: Information for the user**

### **Elocom® Ointment**

### **Mometasone furoate**

**Please read 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 or pharmacist.
- This medicine has been prescribed for you. 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet?**

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

#### **1. What Elocom is and what it is used for**

Elocom 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, Elocom 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. What you need to know before you use Elocom**

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

- if you are allergic (hypersensitive) to mometasone furoate or any of the other ingredients of this medicine (listed in section 6) 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
  - warts
  - ulcerated skin
  - wounds
  - other skin infections

Ask your doctor or pharmacist if you are not sure.

## **Warnings and precautions**

Talk to your doctor or pharmacist before using Elocom:

- if your skin becomes irritated or sensitive after using Elocom, you should stop using it and tell your doctor.
- Contact your doctor if you experience blurred vision or other visual disturbances.

## **Other medicines and Elocom**

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

## **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

## **Elocom Ointment contains propylene glycolstearate**

Elocom Ointment contains propylene glycolstearate, which can cause skin irritation.

## **3. How to use Elocom**

Always use Elocom exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

### **Use in children**

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

### **How much to use**

Usually for adults and children aged 2 and above, a thin layer of Elocom Ointment should be gently rubbed into the affected area of skin once a day.

### **Before using Elocom**

You should always follow these instructions when using Elocom:

- 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 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 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.

#### **If you use more Elocom than you should**

If you (or somebody else) accidentally swallow 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 Elocom**

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 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 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, Elocom 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 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.

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 or pharmacist. This includes any possible side

effects not listed in this leaflet.

## **5. How to store Elocom**

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.
- Do not use this medicine 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 Elocom contains**

- The active substance is mometasone furoate 0.1% w/w.
- The other ingredients are: hexylene glycol; purified water; phosphoric acid; propylene glycol stearate; white wax; white petrolatum.

### **What Elocom looks like and contents of the pack**

The ointment is available in a tube containing 5, 15, 30, 50 and 100 g.

Not all pack sizes may be marketed.

## **7. MARKETING AUTHORISATION HOLDER**

MSD (Pty) Ltd, 117 16th Road, Halfway House 1685, South Africa

## **8. NAME AND ADDRESS OF THE MANUFACTURER**

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

**9. MARKETING AUTHORISATION NUMBER(S):**

<b>ETHIOPIA</b>	SCH/BEL/016
<b>KENYA</b>	7065
<b>NIGERIA (NAFDAC Reg No.)</b>	TBA
<b>TANZANIA</b>	TZ17H0058
<b>UGANDA</b>	3499/13/00
<b>ZAMBIA</b>	042/005
<b>ZIMBABWE</b>	TBA

**10. SCHEDULING STATUS** POM R<sub>x</sub> ONLY**11. DATE OF FIRST AUTHORISATION**

<b>ETHIOPIA</b>	18/08/2016
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<b>NIGERIA</b>	TBA
<b>TANZANIA</b>	09/03/2017
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