

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **MOMETASONE FUROATE 0.1% W/W CREAM**

**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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

The name of your medicine is “Mometasone Furoate 0.1% w/w Cream” but will mostly be referred to as “Mometasone Cream” throughout this leaflet.

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

#### **1. WHAT MOMETASONE CREAM IS AND WHAT IT IS USED FOR**

Mometasone Cream is one of a group of medicines called topical corticosteroids. Mometasone Cream 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 above aged 2 to 18 years, Mometasone 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. WHAT YOU NEED TO KNOW BEFORE YOU USE MOMETASONE CREAM**

##### **Do not use Mometasone Cream**

- if you are allergic (hypersensitive) to mometasone furoate, any of the other ingredients of Mometasone Cream (listed in section 6), 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
  - shingles
  - chickenpox
  - warts
  - ulcerated skin

- wounds and
- other skin infections.

Ask your doctor or pharmacist if you are not sure.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Mometasone Cream

- when this medicine is used on psoriasis, as it may make the condition worse (e.g. a pustular form of the disease may occur). You should let your doctor review your progress at regular intervals, as such treatment needs careful supervision.
- if your skin becomes irritated or sensitive after using Mometasone Cream, you should stop using it and tell your doctor.

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 cream without consulting your prescriber unless your prescriber has previously advised you to 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.

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

### **Children and adolescents**

Mometasone Cream is not for use in children below 2 years of age.

### **Other medicines and Mometasone cream**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, especially if you are taking medicines containing cobicistat, ritonavir (used to treat HIV infection) or itraconazole (used to treat fungal infections).

### **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 taking this medicine.

## **3. HOW TO USE MOMETASONE CREAM**

Always use Mometasone Cream exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Usually for adults and children above 2 years, a thin layer of Mometasone Cream should be gently rubbed into the affected areas of skin once a day.

- You only need to use a small amount of this preparation.
- One fingertip unit (a line from the tip of an adult index finger to the first crease) is enough to cover an area twice the size of an adult hand. Never apply more than this quantity or more often than advised by your doctor or pharmacist.

### **Special care should be used:**

- Do not use it on your face for more than 5 days.
  - Do not apply the cream to children, on any part of the 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.
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- 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 the 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.

### **Use in children**

Mometasone Cream is not recommended for children under the age of 2.

### **If you use more Mometasone Cream 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 or pharmacist.

### **If you forget to use Mometasone Cream**

If you forget to apply the cream at the right time, use it as soon as you remember and then carry on as before.

### **If you stop using Mometasone Cream**

If you have been using Mometasone Cream for a long time and your skin problems 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Mometasone Cream 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 Mometasone Cream:

- 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
  - Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin
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- which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.
- rosacea like redness of the facial skin including spots and visible blood vessels

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. You can also report side effects directly via Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in 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 MOMETASONE CREAM**

Keep this medicine out of the sight and reach of children.

Do not use Mometasone Cream after the expiry date which is stated on the tube and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.  
Do not refrigerate or freeze.

Discard the opened tube with any remaining cream after 12 weeks.

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 Mometasone Furoate 0.1% w/w Cream contains**

- The active substance is mometasone furoate. Each gram of Mometasone Furoate 0.1% w/w Cream contains 1mg of mometasone furoate.
- The other ingredients are hexylene glycol, water, white beeswax (E901), hydrogenated soybean lecithin, titanium dioxide (E171), aluminium starch octenylsuccinate, phosphoric acid, and white soft paraffin which contains traces of all-rac- $\alpha$ -tocopherol.

### **What Mometasone Furoate 0.1% w/w Cream looks like and contents of the pack**

Mometasone Furoate 0.1% w/w Cream is a white to off-white smooth cream.

It is available in tubes containing 10g, 15g, 20g, 30g, 50g, 60g or 100 g of cream.

Not all packs sizes may be marketed.

### **Marketing Authorisation Holder**

Glenmark Pharmaceuticals Europe Limited, Laxmi House, 2 B Draycott Avenue, Kenton, Middlesex HA3 0BU, United Kingdom

### **Manufacturer(s)**

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