

PACKAGE LEAFLET

Package leaflet: Information for the patient

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:

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

1. What Mometasone Furoate is and what it is used for

Mometasone Furoate Cream contains the active substance mometasone furoate, which belongs to a group of medicines called topical corticosteroids. Mometasone Furoate Cream is classified as a “potent corticosteroid”. This medicine is put on the surface of the skin to reduce the redness and itchiness caused by certain skin problems.

In adults and children aged 6 years and over, Mometasone Furoate Cream is used to reduce redness and itchiness caused by certain skin problems such as psoriasis (excluding widespread plaque psoriasis) and some types of 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 Furoate

Do not use Mometasone Furoate:

- if you are allergic to mometasone furoate, or any of the other ingredients of this medicine (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
 - chickenpox

- shingles
- warts
- ulcerated skin
- wounds
- other skin infections

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Mometasone Furoate.

Warnings and precautions

Talk to your doctor or pharmacist before using Mometasone Furoate

- if your skin becomes irritated or sensitive after using Mometasone Furoate, you should stop using it and tell your doctor.

Contact your doctor if you experience blurred visions or other visual disturbances.

Pregnancy and breast-feeding:

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.

Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard.

Do not smoke or go near naked flame due to the risk of severe burns.

Washing clothing and bedding may reduce product build-up but not totally remove it.

Mometasone Furoate Cream contains stearyl alcohol and propylene glycol

This medicine contains 41.1 mg – 44.7 mg stearyl alcohol per gram of cream (4.11 – 4.47% w/w). Stearyl alcohol can cause local skin reactions (e.g. contact dermatitis).

This medicine contains 70 mg propylene glycol monopalmitostearate per gram of cream (7.0% w/w). Propylene glycol may cause skin irritation.

3. How to use Mometasone Furoate

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Mometasone Furoate is not recommended for children under the age of 6.

Adults, including elderly patients and children 6 years of age and older

- A thin layer of cream should be gently applied to the affected area of skin once daily.
- 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.

You should always follow these instructions when using Mometasone Furoate:

- 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 (over 20% of body surface area) 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 and adolescents

Children 6 years of age and over

- Do not use the cream on any part of the child's body, without close supervision of the doctor
- Do not use for more than 5 days
- Do not apply the cream to more than a maximum of 10% of the child's body surface area.

Children below 6 years of age

- Mometasone Furoate 0.1% Cream is not recommended for use in children below 6 years of age.

If you use more Mometasone Furoate than you should

If you (or somebody else) accidentally swallows 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 or 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 Mometasone Furoate

If you forget to use your cream at the right time, use it as soon as you remember, then carry on as instructed by your doctor.

If you stop using Mometasone Furoate

If you have been using Mometasone Furoate 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.

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

4. Possible side effects

Like all medicines, this medicine 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 Furoate:

- 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, blurred vision and small dilated blood vessels.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mometasone Furoate

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 tube or carton after EXP. The expiry date refers to the last day of that month.

This medicine should be disposed of 3 months after first opening.

Do not use the cream if any visible signs of deterioration, such as noticeable changes in colour, are observed. If you are not sure please check with your pharmacist.

Do not throw away any medicine 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 contains:

The active substance is mometasone furoate. Each gram of Mometasone Furoate Cream contains 1 mg of mometasone furoate (0.1% w/w).

The other ingredients are:

- hexylene glycol, stearyl alcohol & macrogol cetostearyl ether, white beeswax, propylene glycol monopalmitostearate, titanium dioxide (E171), aluminium starch octenylsuccinate, dilute phosphoric acid, white soft paraffin and purified water.

What Mometasone Furoate looks like and contents of the pack:

Mometasone Furoate Cream is a white or almost white cream with no visible particles or phase separation.

Within each carton is a tube with a plastic screw cap, which contains either 30 g, 60 g or 100 g of cream.

Not all pack sizes may be marketed.

Marketing authorisation holder:

Auden Mckenzie (Pharma Division) Ltd. Mckenzie House, Bury Street, Ruislip, Middlesex HA4 7TL, UK

Manufacturer:

Tiofarma B.V., Benjamin Franklinstraat 7-9, 3261 LW Oud-Beijerland, The Netherlands

These medicinal products are authorised in the Member States of the EEA under the following names:

United Kingdom:

- Mometasone Furoate 1mg/g Cream
- Mometasone Furoate 1mg/g Ointment

Ireland:

- Mometasone Furoate 0.1% w/w Cream
- Mometasone Furoate 0.1% w/w Ointment

This leaflet was last revised in July 2019.

For information in large print, on tape, on CD or in Braille, phone +44 (0) 1895 627 420.