

Package leaflet: Information for the user

Mometasone Furoate 1mg/g Ointment

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.

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

Mometasone Furoate Ointment belongs to a group of medicines called topical corticosteroids and 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, Mometasone Furoate Ointment 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 Ointment

Do not use Mometasone Furoate Ointment:

- 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.

Ask your doctor or pharmacist if you are not sure.

Warnings and precautions

Talk to your doctor or pharmacist before using Mometasone Furoate Ointment.

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 ointment 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 disturbances.

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

Side effects that may happen with inhaled or oral corticosteroids may also occur with corticosteroids used on the skin, especially in infants and children.

If you use more than the correct amount of ointment and/or use it for longer than is recommended, it can affect the levels of certain hormones in the body, particularly in infants and children.

In adults the changes in hormone levels may lead rarely to puffiness or rounding of the face, weakness, tiredness, and dizziness when standing or sitting down.

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 flames - risk of severe burns. Washing clothing and bedding may reduce product build-up but not totally remove it.

Children

If more than the correct amount of ointment is used and/or it is used for longer than is recommended, it can affect the child's hormones. This may lead to:

- Delayed growth and development
- Puffiness or rounding of the face.

Other medicines and Mometasone Furoate Ointment

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

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.

Mometasone Furoate Ointment contains propylene glycol

May cause skin irritation.

3. How to use Mometasone Furoate Ointment

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

Use in children

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

How much to use

For adults and children aged over 2 and above, a thin layer of ointment should be gently applied to the affected area of skin once daily.

You should always follow these instructions when using Mometasone Furoate Ointment:

- 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 Mometasone Furoate Ointment than you should

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

If you forget to use your ointment at the right time, use it as soon as you remember, then carry on as instructed by your doctor. Do not apply twice as much or use twice in one day to make up for a missed application.

If you stop using Mometasone Furoate Ointment

If you have been using Mometasone Furoate Ointment 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 they will gradually reduce how often you need to use the ointment 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, this medicine can cause side effects, although not everybody gets them.

Very rare (may affect up to 1 in 10,000 people):

- inflammation and/or infection of the hair follicles
- burning sensation of the skin
- itching.

Not known (frequency cannot be estimated from the available data):

- allergic skin reactions
- bacterial and secondary skin infections or pus filled boil
- acne
- thinning of the skin
- red marks with associated prickly heat
- loss of skin colour
- excessive hair growth
- unusual feeling in the skin, such as tingling or numbness in your arms or legs (paraesthesia)
- softening of the skin and stretch marks
- blurred vision.

Other side effects that may occur with topical corticosteroids are:

Not known (frequency cannot be estimated from the available data):

- dry skin, skin irritation, dermatitis, dermatitis around the mouth and small dilated blood vessels.
- 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 which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the 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 Furoate Ointment

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 this medicine if you notice any visible signs of deterioration, such as changes in colour. 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 Ointment contains

The active substance is mometasone furoate. Each gram of Mometasone Furoate Ointment contains 1mg of mometasone furoate (1mg/g).

The other ingredients are: hexylene glycol, white beeswax, propylene glycol monopalmitostearate, dilute phosphoric acid, white soft paraffin and purified water.

What Mometasone Furoate Ointment looks like and contents of the pack

Mometasone Furoate Ointment is an opaque ointment.

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

Not all pack sizes may be marketed.

Marketing authorisation holder

Accord, Barnstaple, EX32 8NS, UK

Manufacturers

Tiofarma B.V., Benjamin Franklinstraat 5-10, 3261 LW Oud-Beijerland, The Netherlands

Tiofarma B.V., Hermanus Boerhaavestraat 1, 3261 ME Oud-Beijerland, The Netherlands

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If you would like a leaflet with larger text, please contact 01271 385257.

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