

Package leaflet: Information for the user
Mometasone Furoate 0.1% w/w 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.

What is in this leaflet:

1. What Mometasone Furoate 0.1% w/w Ointment is and what it is used for
2. What you need to know before you use Mometasone Furoate 0.1% w/w Ointment
3. How to use Mometasone Furoate 0.1% w/w Ointment
4. Possible side effects
5. How to store Mometasone Furoate 0.1% w/w Ointment
6. Contents of the pack and other information

1. WHAT MOMETASONE FUROATE 0.1% W/W OINTMENT IS AND WHAT IT IS USED FOR

Mometasone Furoate 0.1% w/w 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 aged 2 years and older, Mometasone Furoate 0.1% w/w Ointment is used to reduce redness and itchiness caused by certain skin problems called psoriasis and atopic eczema (atopic dermatitis).

Psoriasis is a skin disease in which itchy, scaly, pink patches develop on the elbows, knees, scalp and other parts of the body. Atopic eczema 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 0.1% W/W OINTMENT

Do not use Mometasone Furoate 0.1% w/w Ointment

- If you are allergic to mometasone or any of the other ingredients of this medicine (listed in section 6).
- 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
- perianal and genital itching
- nappy rash
- bacterial infections such as impetigo, tuberculosis (infection of the lung), syphilis (a sexually transmitted disease), viral infections such as warts, shingles and chickenpox (varicella)
- fungal infections such as athlete's foot (red, itchy, flaky skin on the feet),
- infections by parasites
- if you have recently had a reaction to a vaccination
- cold sores
- shingles
- ulcerated skin
- wounds
- other skin infections

Ask your doctor or pharmacist if you are not sure.

Warnings and precautions

If your skin becomes irritated or sensitive after using Mometasone Furoate 0.1% w/w Ointment , you should stop using it and tell your doctor.

Mometasone Furoate 0.1% w/w Ointment is not for use in or around the eye and must not be applied on the eye-lid.

When this medicine is used on psoriasis, 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.

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

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.

Other medicines and Mometasone Furoate 0.1% w/w Ointment

Tell your doctor or pharmacist if you are taking or have recently taken or might take 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 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 taking this medicine.

However, if your doctor does prescribe the ointment to you during pregnancy or while you are breastfeeding, you should avoid using large doses and use only for

a short period. Mometasone Furoate 0.1% w/w Ointment should not be applied to the breast area whilst breastfeeding.

Mometasone Furoate 0.1% w/w Ointment contains propylene glycol and butylated hydroxytoluene (E321)

Mometasone Furoate 0.1% w/w Ointment contains propylene glycol which may cause skin irritations and butylated hydroxytoluene (E321) which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

3. HOW TO USE MOMETASONE FUROATE 0.1% W/W OINTMENT

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

Mometasone Furoate 0.1% w/w Ointment should not be used in children under the age of 2.

Usually for adults and children aged 2 years and older, a thin layer of Mometasone Furoate 0.1% w/w Ointment should be gently rubbed into the affected area of skin once a day.

If you have been prescribed the ointment, 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.

Your doctor should review your treatment at regular intervals.

You should always follow these instructions when using Mometasone Furoate 0.1% w/w Ointment for yourself or your child:

- do not use the ointment on your face for more than 5 days
- you should check with your doctor before covering the treated areas with a bandage or plaster. Treated areas on the face 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

Adults

- You should not use the ointment for long periods (over 3 weeks) or on large areas (over 20% of body surface area).

Children aged 2 years and older

- do not apply the ointment to children, on any part of their body, for more than 3 weeks
- 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
- Treated areas in children should not be covered with a bandage or plaster

Children below 2 years of age

- The ointment should not be used in children under the age of 2.

If you use more Mometasone Furoate 0.1% w/w Ointment 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 or pharmacist.

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 0.1% w/w Ointment

If you forget to apply the ointment at the right time, use it as soon as you remember, then carry on as before. 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 0.1% w/w Ointment

If you have been using Mometasone Furoate 0.1% w/w 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 he 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.

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.

A few people may find that they suffer from some of the following side effects after using Mometasone Furoate 0.1% w/w Ointment:

- 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 which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme via www.mhra.gov.uk/yellowcard

5. HOW TO STORE YOUR MOMETASONE FUROATE 0.1% W/W OINTMENT

Keep this medicine out of the sight and reach of children

Do not use Mometasone Furoate 0.1% w/w Ointment after the expiry date which is stated on the tube and carton after EXP. The expiry date refers to the last day of the month.

Discard the opened tube with any remaining ointment after 12 weeks

Do not store above 30°C. Do not refrigerate or freeze.

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Mometasone Furoate 0.1% w/w Ointment contains

- The active substance is mometasone furoate
Each gram of Mometasone Furoate 0.1% w/w Ointment contains 1mg of mometasone furoate.
- The other ingredients are hexylene glycol, phosphoric acid, concentrated (for pH adjustment), propylene glycol monopalmitostearate, beeswax white, paraffin, white soft ; butylated hydroxytoluene (E321) (as an antioxidant) and water, purified.

What Mometasone Furoate 0.1% w/w Ointment looks like and the contents of the pack

Mometasone Furoate 0.1% w/w Ointment is a translucent white soft ointment. The ointment is filled in aluminium tubes fitted with a white polyethylene piercing screw cap in a cardboard carton.

Pack sizes: Tubes with 10g, 15g, 20g, 30g, 50g, 60g or 100g of ointment.
Not all packs sizes may be marketed.

Marketing Authorisation Holder

Glenmark Pharmaceuticals Europe Ltd,
Laxmi House, 2-B Draycott Avenue, Kenton, Harrow.
Middx, HA3 0BU,
United Kingdom

Manufacturer

Glenmark Pharmaceuticals s.r.o, Hvězdova 1716/2b, 140 78 Praha 4, Czech Republic

Glenmark Pharmaceuticals Europe Limited. Building 2, Croxley Green Business Park, Croxley Green, Hertfordshire, WD18 8YA, UK

This leaflet was last revised in February 2023