

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

### **Mometasone furoate 0.1%w/w Ointment** (mometasone furoate)

**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 is it used for**

Mometasone furoate contains the active substance mometasone furoate, which belongs to a group of medicines called topical corticosteroids (or steroids). Topical corticosteroids can be divided into four degrees of strength or potency: mild, moderate, potent and very potent. Mometasone furoate is classified as a “potent corticosteroid”.

In adults and children, aged 2 years and over, Mometasone furoate is used to reduce symptoms caused by certain inflammatory skin disorders such as psoriasis (excluding widespread plaque psoriasis) and atopic dermatitis. This ointment preparation is generally used to treat very dry, scaly and cracked skin complaints. It is not a cure for your condition, but should help to relieve your symptoms.

#### **2. What you need to know before you use Mometasone furoate**

##### **Do not use Mometasone furoate:**

- If you are allergic to mometasone, other corticosteroids or any of the other ingredients of this medicine (listed in section 6).
- If the skin lesion is infected without simultaneously treating the infection
- On any other skin problems as it could make them worse especially rosacea (a skin condition affecting the face), acne, skin atrophy (thinning of skin), dermatitis around the mouth, perianal and genital itching, nappy rash, bacterial infections such as impetigo, tuberculosis (infection of the skin), syphilis (a sexually transmitted disease), viral infections such as cold sores, shingles, chickenpox, warts, parasitical infections such as scabies, fungal infections such as athlete’s foot (red, itchy, flaky skin on the feet) or thrush, an infection affecting the vagina that can cause discharge and itching or other skin infections.
- On open skin wounds or where the skin is ulcerated.
- If you have recently had a reaction to a vaccination (e.g. for flu).

#### **Warnings and precautions**

Talk to your doctor or pharmacist before or during treatment if any of the following affect you before or whilst using Mometasone furoate.

Corticosteroids can mask, activate or worsen a skin infection.

If irritation or sensitisation develops with the use of Mometasone, you should tell your doctor immediately.

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.

Whilst using Mometasone furoate if an infection develops in the skin you are treating then you should talk to your doctor as soon as possible. If the infection does not respond to the anti-infective treatment you may need to stop applying Mometasone furoate until the infection is controlled.

Application of Mometasone furoate to a large area of the body or under occlusion (for example for children under a nappy, under or in the skin folds or under dressings) can increase the risk of the steroid being absorbed through the skin. If absorbed, mometasone furoate can cause some side effects in the body. If you need to apply to a large area, under dressings or a nappy or in the skin folds ask your doctor or pharmacist for advice before applying.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

The ointment should not be put on the eyelids. Take care not to get any ointment in the eye as, very rarely, cataracts (clouding of the eye lens) or glaucoma (raised pressure in the eye) can occur.

Normally you should also not apply to the face. If your doctor recommends applying to the face, normally this should be for no more than 5 days.

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

During treatment with Mometasone furoate in the genital or anal area, the excipient white soft paraffin and simultaneous use of latex condoms can lead to a reduction in tensile strength, increasing the risk of condom failure.

Mometasone furoate may be used for children over 2 years of age, however special care should be used (see details below).

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

### **Other medicines and Mometasone furoate**

Tell your doctor or pharmacist if you are taking or using, have recently taken or used or might take or use any other medicines, including medicines obtained without a prescription and any other remedies or dietary supplements such as vitamins. Ask your doctor for advice before taking any medicine.

### **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.

If your doctor does prescribe the ointment to you during pregnancy or while you are breast-feeding, you should avoid using large doses and use only for a short period. It is not known if the medicine may be present in breast milk after you have applied to the skin. To prevent accidental indigestion, Mometasone furoate should not be applied to the breast area whilst breast-feeding.

Ask your doctor for advice before taking or using any medicine.

### **Mometasone furoate contains propylene glycol and butylhydroxytoluene**

Mometasone furoate contains propylene glycol, which may cause skin irritation, and butylhydroxytoluene (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**

#### **Type of administration**

Mometasone furoate is for cutaneous use (use on the skin).

This medicinal product is for external use only.

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 is not recommended for children under the age of 2.

Your doctor should review your treatment at regular intervals.

#### **Adults, including older people and children 2 years of age and older**

The recommended dose is a thin layer of ointment gently applied to the affected areas of skin once daily.

Normally, 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**

- If recommended to be applied to the face, do not use the ointment for more than 5 days without close supervision of your doctor.
- You should not use the ointment on large areas of the body (over 20% of body surface area) or for a long time (for example every day for over 3 weeks).
- Avoid getting the ointment in your eyes.
- Unless directed by your doctor, do not apply a bandage or dressing to the area being treated. This will increase absorption of the preparation and increase possible side effects.

#### **Use in children and adolescents:**

- Do not use the ointment for children over 2 years of age, on any part of their body, without close supervision of the doctor. Do not apply the ointment to more than a maximum of 10% of the child's body surface area for no more than 5 days. Do not apply the ointment under a child's nappy, as this may make it easier for the medicine to pass through the skin (see also Warnings and precautions).

#### **If you use more Mometasone furoate than you should**

If you accidentally swallow the ointment, it should not normally produce any undesirable effects. 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 followed the dosage instructions or your doctor's advice and have used the ointment too frequently and/or for a long time, you should tell your doctor or pharmacist.

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

If you forget to apply the ointment at the scheduled time, do it as soon as you remember and 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**

Do not stop treatment suddenly if you have used it for a long time since this may be harmful. Treatment should be stopped gradually, as advised by your doctor as you may develop a severe rash that is very red, itchy and painful. To stop using Mometasone, gradually use less with each application or use Mometasone less frequently (e.g. every other day).

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 your symptoms do not begin to improve after using this preparation as instructed by your doctor or if they get worse, check with your doctor.

**If you notice any of the following side effects, stop taking this medicine and contact your doctor or go to the nearest hospital casualty department straight away:**

- Cushing's syndrome which may include many symptoms such as rapid weight gain, especially of the trunk and face, and general weakness, particularly in children treated with corticosteroids as they can absorb more of this medicine through the skin.

Other side effects in children and adults that have been reported with the use of topical corticosteroids include:

##### **Common (may affect up to 1 in 10 people):**

- Tingling or stinging sensation

##### **Uncommon (may affect up to 1 in 100 people):**

- Formation of small nodules and pimples
- After prolonged and intensive treatment thinning of the skin (skin atrophy) may occur which can lead to increased uptake and increased risk of side effects, ruptures in superficial blood vessels, skin infections, irregular skin marks or stripes (including stretch marks) and rosacea like redness of the facial skin.

##### **Rare (may affect up to 1 in 1000 people):**

- Treatment of large body areas, can have an impact on the adrenal glands. This effect disappears when treatment is discontinued.
- Excessive hair growth (hypertrichosis)
- Allergic reactions in the form of increased redness, itching, tingling and skin irritation

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

- Inflammation of the skin follicles
- Burning sensations
- Itching

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

- An infection of the skin, or pus-filled blisters/boil. You should talk to your doctor as soon as possible (see also Warning and precautions)
- Tingling or numbness in your arms and legs (paraesthesia)
- Application site pain or irritation
- Visible small blood vessels under the skin, thinning of the skin, skin inflammation (including acne type reactions), a red itchy scaly rash which may be around the mouth, changes in skin colour, purple or dark blue discoloration of the skin, sensitisation, stinging, dryness, maceration of the skin (softening and whitening), prickly heat (a very itchy rash)
- Blurred vision

Increased usage, treatment of large areas of skin, long term use and use under a dressing may increase the risk of side effects.

Corticosteroids may affect the normal production of steroids in the body. This is more likely to happen if high doses are being used over a long period of time.

**Additional side effects in children and adolescents**

Children on long-term treatment may grow more slowly than others. Your doctor will help prevent this happening by prescribing the lowest dose of steroid at which your symptoms are well controlled.

**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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

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 use this medicine 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.

Do not store above 30°C.

Discard the opened tube with any remaining ointment 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 further information**

**What Mometasone furoate contains**

The active substance is mometasone furoate.

Each gram of Mometasone furoate contains 1 mg of the active substance mometasone furoate.

The other ingredients are hexylene glycol; phosphoric acid, concentrated (for pH adjustment); propylene glycol monopalmitostearate; beeswax, white; paraffin, white soft; butylhydroxytoluene (E321) (as an antioxidant) and water, purified.

### **What Mometasone furoate looks like and contents of the pack**

Mometasone furoate is a clear white soft, smooth ointment. The ointment is filled in aluminium tubes fitted with a white polyethylene piercing screw cap in a cardboard carton.

Pack sizes: Tubes with 10 g, 15 g, 20 g, 30 g, 50 g, 60 g or 100 g of ointment.

Not all packs sizes may be marketed.

### **Marketing Authorisation Holder**

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

### **Manufacturer**

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange State, Dublin 13, Ireland

Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire, EN6 1TL United Kingdom

Viartis UK Healthcare Limited, Building 20, Station Close, Potters Bar, EN6 1TL, United Kingdom

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