

Package Leaflet: Information for the User

Eumovate Ointment **clobetasone butyrate**

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

1. What Eumovate is and what it is used for

Eumovate contains a medicine called clobetasone butyrate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.

Eumovate is used to:

- help reduce the redness and itchiness of certain skin problems. It is used for mild skin problems or to keep your skin problem under control. These skin problems include eczema, dermatitis, nappy rash or insect bites.
- help reduce inflammation of the outer ear.

2. What you need to know before you use Eumovate

Do not use Eumovate:

- if you are allergic to clobetasone butyrate or any of the other ingredients of this medicine (listed in Section 6)
- to treat any of the following skin problems, it could make them worse:
 - infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
 - acne
 - severe flushing of skin on and around your nose (rosacea)
 - itchy skin which is not inflamed

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

Warnings and precautions

Talk to your doctor or pharmacist before using Eumovate if:

- you have previously had an allergic reaction with another steroid.
- using for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- you have been advised by your doctor to use this medicine under an occlusive dressing (including a child's nappy). Make sure that the skin is cleansed before a fresh dressing is applied to prevent infections. Occlusive dressings (including a child's nappy) make it easier for the active ingredient to pass through the skin, making it possible to accidentally use too much.
- you are applying to thin skin such as the face, as skin is thinner and may absorb larger amounts. Dressing or bandages should not be used on the face where the ointment is applied.
- you are applying to the face over a long period of time as it may cause skin thinning.
- you are applying the ointment on broken skin or within the skin folds.
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the ointment repeatedly enters the eye.
- you experience blurred vision or other visual disturbances.
- you accidentally swallow a large amount of Eumovate, rinse the mouth out with plenty of water and contact a doctor or pharmacist for advice **immediately**.
- if an infection develops (see section 4, Possible side effects)

Children

- Treatment in children under 12 years of age should not normally exceed 7 days.
- Prolonged daily treatment in children can affect their growth. Continuous daily treatment for longer than 4 weeks is not recommended.

If this product comes into contact with dressings, clothing and bedding the fabric can be easily ignited with a naked flame. You should keep away from fire when using this product.

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

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/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 Eumovate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine, especially if you are taking ritonavir and itraconazole medications.

Pregnancy, breast-feeding and fertility

If you are pregnant or are 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. Whilst using Eumovate do not smoke or go near naked flames due to the risk of severe burns. Fabric (clothing, bedding, dressing 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.

3. How to use Eumovate

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

Using this medicine

- You usually apply Eumovate up to 2 times a day. This may be reduced as your skin begins to get better.
- This ointment is for use on your skin only.
- Do not use on large areas of the body for a long time (such as every day for many weeks or months) - unless your doctor tells you to.
- If you are using an emollient (moisturising) preparation allow time for Eumovate to be absorbed after each application before applying the emollient.
- If you are applying the ointment on someone else make sure you wash your hands after use or wear disposable plastic gloves.
- If your skin problem does not improve after 4 weeks, talk to your doctor.

Guidance on how to apply the ointment

- 1 Wash your hands.
- 2 Apply a thin layer to the affected area(s) and gently rub into the skin until it has all disappeared. You can measure how much Eumovate to use with your fingertip. For children you will need to use less ointment but still use an adult finger to measure out the fingertip unit. This picture shows one fingertip unit.

[Pictogram of 1 fingertip unit]

- 3 Unless you are meant to apply the ointment to your hands as a part of the treatment, wash them again after using the ointment.

For an adult

[Pictogram of an adult with fingertip units to be used as per text below with arrows pointing to relevant body part]

Face and neck:

2 ½ fingertip units.

Back: **7 fingertip units.**

Front: **7 fingertip units.**

One arm (not including the hand):

3 fingertip units.

Both sides of one hand:

1 fingertip unit.

One leg (not including the foot):

6 fingertip units

One foot:

2 fingertip units.

Do not worry if you find you need a little more or less than this. It is only a rough guide.

For a child

Number of fingertip units needed					
Child's age	Face and neck	Arm and hand	Leg and foot	Front	Back including buttocks
3-6 months	1	1	1 ½	1	1 ½
1-2 years	1 ½	1 ½	2	2	3
3-5 years	1 ½	2	3	3	3 ½
6-10 years	2	2 ½	4 ½	3 ½	5

- Do not use on children younger than 12 years unless advised by a doctor.
- If the condition worsens or does not improve within 7 days, consult a doctor.
- Once the condition improves, reduce both the amount applied and the frequency of application to the minimum necessary to relieve symptoms.
- Do not use every day for more than 4 weeks at a time.

If you apply Eumovate to your face

You should only apply the ointment to your face if your doctor tells you to. The ointment should not be used for too long as the skin on your face thins easily. **Do not let the ointment get into your eyes.**

If you use more Eumovate than you should

If you apply a lot or if a lot is accidentally swallowed, it could make you ill. Talk to your doctor or go to hospital as soon as possible.

If you forget to use Eumovate

If you forget to apply your ointment, apply it as soon as you remember. If it is close to the time you are next meant to apply it, wait until this time.

If you stop using Eumovate

If you use Eumovate regularly make sure you talk to your doctor before you stop using it as your condition may get worse if stopped suddenly.

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.

Stop using Eumovate and tell your doctor immediately if:

- you find that your skin condition gets worse, you develop a generalised rash or your skin becomes swollen during treatment. You may be allergic to the ointment, have an infection or need other treatment.

Other side effects you may notice when using Eumovate include:**Very rare** (may affect up to 1 in 10,000 people)

- an increased risk of skin infection
- an allergic skin reaction where the ointment is applied
- a feeling of burning, irritation or itching where the ointment is applied
- rash, itchy bumpy skin or redness of the skin
- increased hair growth and changes in skin colour
- thinning of your skin and it may also damage more easily
- weight gain, rounding of the face
- delayed weight gain or slowing of growth in children
- bones can become thin, weak and break easily
- cloudy lens in the eye (cataract) or increased pressure in eye (glaucoma)
- increased blood sugar levels or sugar in the urine
- high blood pressure

Not Known (frequency cannot be estimated from the available data)

- blurred vision
- Steroid withdrawal reaction: If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after 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.

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Eumovate Ointment is classed as a moderate corticosteroid. Your

healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

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.

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

5. How to store Eumovate

- Keep out of the sight and reach of children.
- 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.
- Do not store above 25°C.
- 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 Eumovate contains

- The active ingredient is clobetasone butyrate. Each 1 g contains 0.5 mg of clobetasone butyrate (0.05% w/w).
- The other ingredients are liquid paraffin and white soft paraffin.

What Eumovate looks like and contents of the pack

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

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Glaxo Wellcome UK Ltd, GSK Medicines Research Centre, Gunnels Wood Road, Stevenage, Hertfordshire, SG1 2NY, UK

Manufacturer

Glaxo Operations UK Ltd, Harmire Road, Barnard Castle, Durham DL12 8DT

More Information

If you have any questions or are not sure about anything, ask your doctor or pharmacist who will advise you.

You may be able to find out more information from books in public libraries.

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name **Eumovate Ointment**

Reference number 10949/0037

This is a service provided by the Royal National Institute of Blind People.

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