

**EUMOVATE® CREAM/
CLOBETASONE BUTYRATE 0.05% w/w CREAM
(Clobetasone butyrate)
Patient Information Leaflet**

This product is available as the above names, but will be referred to throughout this leaflet as Eumovate.

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:

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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.

Warning 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 are applying the cream under an airtight dressing, including a child's nappy. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much cream.
- you have psoriasis, your doctor will want to see you more often.
- you are applying the cream on broken skin or within the skin folds.
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the cream repeatedly enters the eye.
- you are applying to thin skin such as the face or on children as their skin is thinner than adults and as a result may absorb larger amounts.
- dressing or bandages should not be used on children or on the face where the cream is applied.
- you are applying to the face over a long period of time as it may cause skin thinning.
- use on children should be limited to 7 days.
- you accidentally swallow. Rinse the mouth out with plenty of water and contact a doctor or pharmacist for advice **immediately**.

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

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 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.

Eumovate Cream contains chlorocresol and cetostearyl alcohol

Eumovate cream contains chlorocresol which may cause allergic reactions and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

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 cream 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 cream 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 cream

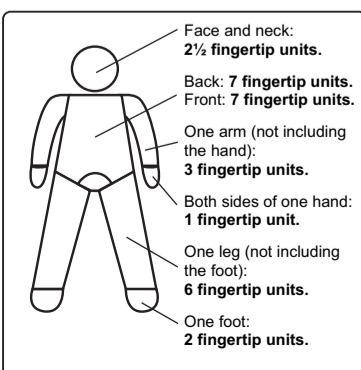
- 1 Wash your hands.
- 2 Apply a thin layer to the affected area(s) and gently rub into the skin until it has all disappeared. You can measure how much Eumovate to use with your fingertip. For children you will need to use less cream but still use an adult finger to measure out the fingertip unit. This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



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

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

For an adult



For a child

Number of fingertip units needed					
Childs age	Face and neck	Arm and hand	Leg and foot	Front	Back including buttocks
3-6 months	1	1	1½	1	1½
1-2 years	1½	1½	2	2	3
3-5 years	1½	2	3	3	3½
6-10 years	2	2½	4½	3½	5

- If the condition does not improve within 7 days, consult your doctor. Continuous daily treatment for longer than 4 weeks is not recommended.

If you apply Eumovate to your face

You should only apply the cream to your face if your doctor tells you to. The cream should not be used for too long as the skin on your face thins easily. **Do not let the cream 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 cream, 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 cream, have an infection or need other treatment.
- you have psoriasis and get raised bumps with pus under the skin. This can happen during or after treatment and is known as pustular psoriasis.

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 cream is applied.
- a feeling of burning, irritation or itching where the cream 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

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 after the expiry date on the tube or carton (Exp). The expiry date refers to the last day of that month.
- Eumovate cream/Clobetasone Butyrate 0.05% w/w cream should not be stored above 25°C.
- If the cream becomes discoloured or shows any other signs of deterioration, you should ask your doctor or pharmacist before using it.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Your medicine is called Eumovate cream/Clobetasone Butyrate 0.05% w/w cream. It contains the active ingredient, Clobetasone butyrate 0.05% w/w in a white cream base.

Eumovate cream/Clobetasone Butyrate 0.05% w/w cream also contains the following: glyceryl monostearate, cetostearyl alcohol, dimethicone, glycerol, Arlacel 165, chlorocresol, sodium citrate, citric acid, beeswax substitute and purified water.

Eumovate cream/Clobetasone Butyrate 0.05% w/w cream is available as tubes of 30g.

POM

PL No: 6464/1512

This product is manufactured by Glaxo Operations UK Ltd, Barnard Castle, Co Durham, UK and procured within the EU and repackaged by the Product Licence holder:

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Leaflet revision and issue date (Ref.) 26.08.2014

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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.