

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a physician's prescription only

Eumovate Cream

Each 1 g contains 0.5 mg of clobetasone butyrate (0.05% w/w).

A list of the additional ingredients is detailed in section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Eumovate Cream is indicated for the relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses. These include the following: Atopic dermatitis, Irritant or allergic contact dermatitis, Seborrhoeic dermatitis, Nappy rash, Photodermatitis, Otitis externa, Prurigo nodularis and Insect bite reactions.

Therapeutic group: Corticosteroids

2. Before using the medicine

Do not use the medicine:

- if you are sensitive (allergic) to the active ingredient clobetasone butyrate or any of the additional ingredients contained in the medicine (as 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 concurrently with an anti-infective medicine)
 - acne
 - severe flushing of the skin on and around the 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 physician or pharmacist before using Eumovate Cream.

Special warnings regarding the use of the medicine

Talk to your physician or pharmacist before using Eumovate Cream if:

- you have previously had an allergic reaction with another steroid.
- you are using Eumovate Cream for a chronic leg ulcer as you may be at increased risk of a local allergic reaction or infection.
- you have been instructed by your physician to apply this medicine under an occlusive dressing (including a child's nappy). To prevent infections, make sure that the skin is clean before putting on a fresh dressing. Occlusive dressings (including a child's nappy) make it easier for the active ingredient to be absorbed through the skin, and therefore, may accidentally cause you to use too high a dosage.

- you are applying to thin skin such as the face, as the skin is thinner and may absorb larger amounts. Dressings or bandages should not be used 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.
- you have psoriasis; your physician will want to see you more often.
- you are applying the cream on broken skin or within the skin folds.
- you are applying near the eyes or on the eyelids, as cataracts or glaucoma may result if the cream repeatedly enters the eye.
- if you accidentally swallowed a large amount of Eumovate Cream, rinse out the mouth with plenty of water and contact a physician or pharmacist for advice **immediately**.
- if an infection develops (see section 4, Side effects).
- **if there is renal or hepatic impairment:** In the case of systemic exposure (when application is performed over large body surfaces for extended periods of time), clearance of the medicines may be decreased; therefore, apply the minimum amount for a short period of time to achieve clinical benefit.

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

Children

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

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

Other medicines and Eumovate Cream

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist, especially if you are taking ritonavir and itraconazole medications.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask your physician or pharmacist for advice before taking this medicine.

Important information about some of the ingredients in this medicine

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

3. How should you use the medicine?

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure.

The dosage and treatment regimen will be determined by the physician only. The usual dosage is generally:

- Applying Eumovate Cream 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) - without instruction from the physician.
- If you are using a moisturizing preparation, allow time for Eumovate Cream to be absorbed into the skin after each application, before applying the moisturizing preparation.
- If you are applying the cream on someone else, make sure you wash your hands after use or wear disposable plastic gloves.
- The cream can be used on infants from the age of 3 months.
- If your skin problem does not improve within 4 weeks, consult with the physician.

Do not swallow

For external use only

Do not exceed the recommended dose

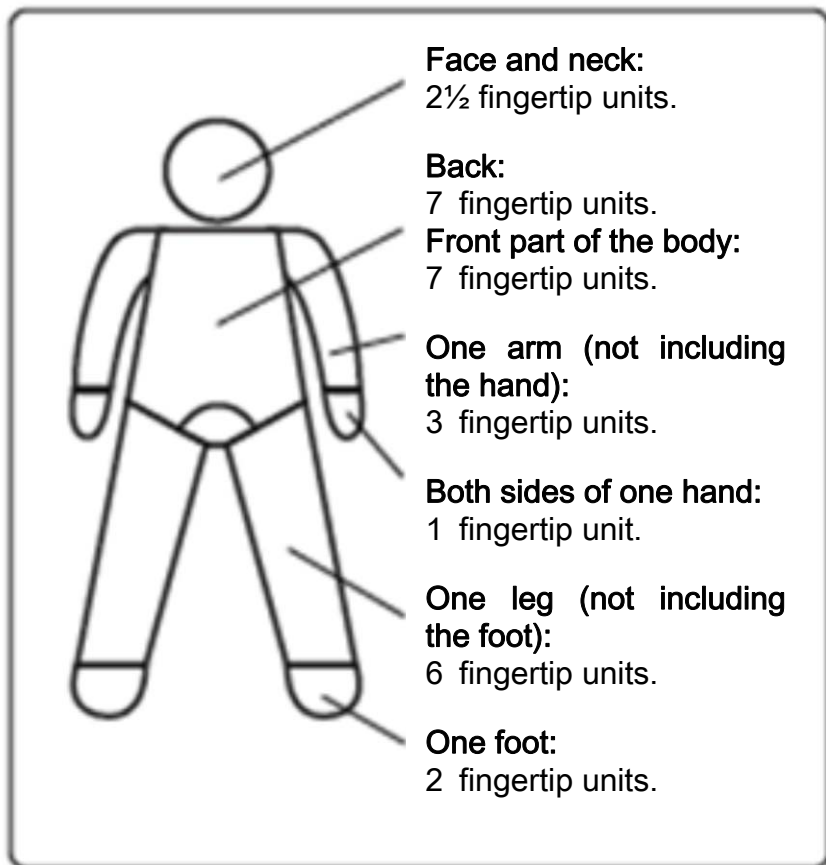
Guidance on how to apply the cream

1. Wash your hands.
2. Apply a thin layer to the affected area(s) and gently rub until it all absorbs into the skin. You can measure how much Eumovate Cream to use with your fingertip. For children, you will need to use less cream but still use an adult finger to measure the fingertip unit. The following 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.

Use in adults



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

Use in children

Number of fingertip units needed					
Child's age	Face and neck	Arm and hand	Leg and foot	Front part of body	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 under 12 years of age unless instructed to do so by a physician.
- If the condition worsens or does not improve within 7 days, consult a physician.
- 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 Cream to your face

You should only apply the cream to your face if your physician 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 have accidentally taken a higher dosage

If you accidentally applied or swallowed too much cream, it could make you ill. Refer to your physician or go to a hospital as soon as possible.

If a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine

If you forgot 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.

Adhere to the treatment regimen recommended by the physician.

If you stop using Eumovate Cream

If you use Eumovate Cream regularly, talk to your physician before you stop using it. Your condition may get worse if the treatment is stopped suddenly.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the physician or the pharmacist.

4. Side effects

As with any medicine, use of Eumovate Cream may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Stop using Eumovate Cream and tell your physician immediately if:

- you find that your skin condition gets worse, you develop a generalized rash or your skin becomes swollen during the 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.

Additional side effects you may notice when using Eumovate Cream include:

Very rare side effects (may occur in 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 color
- 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 thin, weaken and break easily
- cloudy lenses in the eyes (cataract) or increased pressure in the eye (glaucoma)
- increased blood sugar levels or sugar in the urine
- high blood pressure.

Side effects of unknown frequency

- blurred vision

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, you should consult with the physician.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>.

5. How should the medicine be stored?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Can be used for 12 weeks after first opening.

6. Additional information

- In addition to the active ingredient, the medicine also contains:
Glycerol, glycerol monostearate, cetostearyl alcohol, beeswax substitute 6621, Arlacel 165, dimeticone 20, chlorocresol, sodium citrate, citric acid monohydrate and purified water.
- What the medicine looks like and the content of the package:
Within each carton, there is a tube with a plastic screw cap, which contains either 25, 30 or 100 g of cream.
Not all pack sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Operations UK Limited, Barnard Castle, UK.
- The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health in September 2016, and was updated in May 2018, in accordance with the Ministry of Health guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 043-34-23785

Trade marks are owned by or licensed to the GSK group of companies.

©2018 GSK group of companies or its licensor.

Eum Cre PT v6B