

Reason for Update: Type Iain Project Pine CMC update (PZN address is grey shaded therefore no live artwork impacted thus no change to date in PIL)

Market: Ireland

Agency Approval Date: 30/06/2022 (imp date for Type IAINs)

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Text Issue and Draft No.: Issue 9 draft 1

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

### **Eumovate Cream 0.05% w/w** 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.
- In this leaflet, Eumovate Cream 0.05% w/w will be called Eumovate.

#### **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 which belongs to a group of medicines called corticosteroids. It helps to reduce redness, swelling and irritation of the skin. (These should not be confused with “anabolic” steroids misused by some body builders and athletes and taken as tablets or injections).

Eumovate relieves the symptoms of certain skin problems including:

- eczema including seborrhoeic eczema (red skin with greasy looking white or yellowish-coloured scales) and a type of skin reaction triggered by exposure to sunlight (photodermatitis)
- skin rash due to allergy or a substance that irritates your skin (irritant or allergic contact dermatitis)
- dermatitis
- inflammation of the outer ear (otitis externa)
- itchy nodules on the arms or legs (prurigo nodularis)
- insect bite reactions

For infants and children, Eumovate is used for dermatitis that has not responded to milder steroid creams or ointments.

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## 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:
  - infection of the skin (unless the infection is being treated with an anti-infective medicine at the same time)
  - rosacea (a facial skin condition where the nose, cheeks, chin, forehead or entire face are unusually red, with or without tiny visible blood vessels, bumps (papules) or pus-filled bumps (pustules))
  - acne
  - perioral dermatoses (tiny red bumps around the mouth)
  - itchy skin which is not inflamed.
- with occlusive dressings or under nappies in children under 1 year of age.

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 corticosteroid or any of the ingredients (listed in section 6).
- If you have eczema around a leg ulcer, use of a topical corticosteroid may increase the risk of an allergic reaction or an infection around the ulcer.
- Only use Eumovate for as long as your doctor recommends. Avoid long term continuous treatment for longer than 4 weeks. If your condition does not improve after 4 weeks of treatment, speak to your doctor.
- Take care when applying Eumovate to eyelids to make sure it does not get into your eyes as there may be a risk of developing cataract and glaucoma.
- Take care when applying Eumovate to the face over a long period of time as it may cause skin thinning.
- Only use an occlusive dressing (including a child's nappy) over this medicine if your doctor has told you to.
- If 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.
- For external use only. Keep this and all medicines out of reach of children. If a child accidentally swallows a large amount of Eumovate, rinse their mouth out with plenty of water and contact a doctor or pharmacist for advice **immediately** (see section 3, **If you use more Eumovate than you should**)
- **Contact your doctor** if an infection develops (see section 4, Possible side effects)

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

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

### **Children**

- Do not use in children under 1 year of age with occlusive dressings or under nappies because of the risk of absorbing too much active ingredient which could affect the child's growth.
- 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.

### **Other medicines and Eumovate**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may affect how Eumovate works, or make it more likely that you'll have side effects. Examples of these medicines include:

- ritonavir and itraconazole

### **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 you do use Eumovate when breast-feeding, **do not use it on your breast area** to ensure that the **baby does not accidentally get Eumovate in their mouth**.

### **Important information about some of the ingredients in Eumovate**

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

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 or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **Using this medicine**

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- You usually apply Eumovate once or twice 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 more than four weeks at a time) - 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 worsens or does not improve within 4 weeks, talk to your doctor.

### **Guidance on how to apply the cream**

- 1 Wash your hands.
- 2 Apply a thin layer of cream and gently rub into the skin until it has all disappeared, using only enough to cover the entire affected area.
- 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 children**

- 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.
- Do not use in children under 1 year of age with occlusive dressings or under nappies.

### **If you use more Eumovate than you should**

If, by mistake on a few occasions you use more than you should, do not worry. If you continue to use too much over a period of time you may develop symptoms such as: increased body hair, changes to the colour of your skin, skin thinning, weight gain, moon face/rounding of the face. If any of these symptoms occur or you think you have used too much of this medicine talk to your doctor or go to hospital as soon as possible.

If a lot is accidentally swallowed, it could make you ill. If you do swallow a large amount of Eumovate, rinse your mouth out with plenty of water and 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. Do not apply extra Eumovate to make up for missed doses.

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### **If you stop using Eumovate**

If you use Eumovate regularly make sure you talk to your doctor before you stop using it.

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. Side effects will affect your skin and may affect other parts of your body if a sufficient quantity of medicine is absorbed through the skin and enters your blood stream.

### **Stop using Eumovate and tell your doctor as soon as possible if:**

- you find that your skin condition gets worse or becomes swollen during treatment. You may be allergic to the cream, 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)

Use of Eumovate for a long period of time, or use under an airtight dressing, may cause the following symptoms:

- increased weight
- moon face/rounding of the face
- obesity
- skin thinning
- changes to the colour of your skin
- increased body hair

Other very rare skin reactions that may occur are:

- allergic reaction at the site of application
- itching
- local skin burning
- worsening of condition
- redness
- rash or hives
- skin infection

In children also look out for the following symptoms:

- delayed weight gain
- slow growth

Very rare side effects that may show up in blood tests or when your doctor gives you a medical examination:

- a decrease in the level of the hormone cortisol in your blood

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- increased levels of sugar in your blood or urine
- high blood pressure
- cloudy lens in the eye (cataract)
- increased pressure in the eye (glaucoma)
- weakening of the bones through gradual loss of mineral (osteoporosis); additional tests may be needed after your medical examination to confirm if you have this condition

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

- blurred vision

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: [www.hpra.ie](http://www.hpra.ie).

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

## **5. How to store Eumovate**

- Keep this medicine out of the sight and reach of children.
- Do not use Eumovate 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 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 other information**

### **What Eumovate contains**

- The active substance is clobetasone butyrate. Each 1 g contains 0.5 mg of clobetasone butyrate (0.05% w/w).
- The other ingredients are glycerol, glycerol monostearate, cetostearyl alcohol (see section 2), beeswax substitute 6621 (contains paraffin), Arlacel 165, dimeticone 20, chlorocresol (see section 2), sodium citrate, citric acid monohydrate and purified water.

### **What Eumovate looks like and contents of the pack**

Within each carton is a tube with a plastic screw cap, which contains 30 g of a smooth white cream.

### **Marketing Authorisation Holder and Manufacturer**

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### **Marketing Authorisation Holder**

GlaxoSmithKline (Ireland) Ltd, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

### **Manufacturer**

Delpharm Poznań Spółka Akcyjna, ul. Grunwaldzka 189, 60-322 Poznań, Poland

GlaxoSmithKline Trading Services Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland

**This leaflet was last revised in September 2021.**

### **Other sources of information**

This package leaflet is available in formats that are suitable for the blind or partially sighted. Such formats are available on request.

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