

## Package Leaflet: Information for the user

### **Dermovate Ointment** **clobetasol propionate**

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

### **1. What Dermovate is and what it is used for**

Dermovate contains a medicine called clobetasol propionate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.

Dermovate is used to help reduce the redness and itchiness of certain skin problems. These skin problems include:

- frequently relapsing eczema
- psoriasis (thickened patches of inflamed, red skin, often covered by silvery scales), excluding widespread plaque psoriasis
- lichen planus (a skin disease that causes itchy, reddish-purple, flat-topped bumps on the wrists, forearms or lower legs)
- discoid lupus erythematosus (a disease of the skin most often affecting the face, ears and scalp causing scarring and increased sensitivity of the affected skin to sunlight)
- dermatitis and other skin conditions that have not responded to milder steroid creams or ointments.

### **2. What you need to know before you use Dermovate**

#### **Do not use Dermovate:**

- if you are allergic (hypersensitive) to clobetasol propionate or any of the other ingredients of this medicine (listed in Section 6)
- on a child under 1 year of age
- to treat any of the following skin problems, it could make them worse:
  - acne
  - severe flushing of skin on and around your nose (rosacea)

- spotty red rash around your mouth (perioral dermatitis)
- itching around your anus or genitals (penis or vagina)
- infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
- itchy skin which is not inflamed
- widespread plaque psoriasis, except single lesions.

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

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Dermovate if:

- you experience newly developed bone pain or worsening of previous bone symptoms during a treatment with Dermovate especially if you have been using Dermovate for a prolonged time or repeatedly.
- you use other oral/topical medication containing corticosteroids or medication intended to control your immune system (e.g. for autoimmune disease or after a transplantation). Combining Dermovate with these medicines may result in serious infections.
- you have previously had an allergic reaction with another steroid
- you are applying the ointment 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 ointment.
- make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.
- you are applying the ointment on broken or damaged skin or within the skin folds.
- you are applying to a large surface area.
- you have psoriasis, your doctor will want to see you more often.
- you are using around a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the ointment repeatedly enters the eye.
- you are applying to thin skin such as the face, as Dermovate may cause skin thinning. Use on the face should be limited to 5 days. Dressings or bandages should not be used on the face where the ointment is applied.

If an infection develops during the use of this medicine, talk to your doctor or pharmacist.

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.

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.

### **Children**

- Do not use this medicine in children under 1 year of age.
- Avoid continuous treatment for a long period of time in infants and children over 1 year of age, as their skin is thinner than adults and as a result may absorb larger amounts.
- Use on children should be limited to 5 days and reviewed weekly.
- Dressings or bandages should not be used on children where the ointment is applied.

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.

### **Other medicines and Dermovate**

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 planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

### **Dermovate Ointment contains 50 mg propylene glycol per gram of product.**

Propylene glycol may cause skin irritation.

Whilst using Dermovate 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 Dermovate**

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 a thin layer of Dermovate once or twice a day. This may be reduced as your skin begins to get better, or stopped when it is better. Your doctor may prescribe a weaker steroid for you to use instead.
- If you are also using an emollient (moisturiser), allow time for Dermovate to be absorbed into your skin before applying the emollient.
- This ointment is for use on your skin only.

- Do not use for more than 4 weeks without talking to your doctor. If you need treatment for a long time, your doctor may decide you need to use a milder cream or ointment.
- If your skin problem worsens or does not improve within 2 to 4 weeks, talk to your doctor.
- The germs that cause infections like the warm and moist conditions under dressings. If directed to cover the treated area with a dressing, always clean the skin before a fresh dressing is put on to help prevent infection of the skin beneath the dressing.
- If you are applying the ointment on someone else make sure you wash your hands after use or wear disposable plastic gloves.

### **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 Dermovate 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 adolescents (≥ 12 years old) and adults**

#### **[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 aged 1 – 10**

Number of fingertip units needed					
Child's age	Face and neck	Arm and hand	Leg and foot	Front	Back including buttocks
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

### Use in children

- Do not use this medicine on children under 1 year of age.
- It is especially important in children not to exceed the prescribed amount.
- A course of treatment for a child should not normally last more than 5 days unless your doctor has told you to use it for longer. Your doctor may want to see the child every week, whilst using the ointment.
- Dressings or bandages should not be used on children where the ointment is applied.

### If you have psoriasis

If you have thick patches of psoriasis on your elbows or knees, your doctor may suggest applying the ointment under an airtight dressing. It will only be at night to help the ointment to start working. After a short period of time you will then apply the ointment as normal.

### If you apply Dermovate to your face

You should only apply the ointment to your face if your doctor tells you to. It should be limited to 5 days, as the skin on your face thins easily. Dressings or bandages should not be used on the face where the ointment is applied.

**Do not let the ointment get into your eyes.** If it does, wash it out with plenty of water.

### If you use more Dermovate than you should

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

### If you forget to use Dermovate

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. Do not apply extra Dermovate to make up for a missed dose.

### If you stop using Dermovate

If you use Dermovate 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 Dermovate and tell your doctor immediately if:**

- you find that your skin problem 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.
- you have psoriasis and get raised bumps with pus under the skin. This can happen during or after the treatment and is known as pustular psoriasis.

##### **Other side effects you may notice when using Dermovate include:**

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

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

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

- skin thinning, stretch marks may develop.
- blood vessels under the surface of your skin may become more noticeable.

##### **Very Rare (may affect up to 1 in 10,000 people)**

Use of Dermovate 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
- skin wrinkling
- skin dryness
- changes to the colour of your skin
- increased body hair
- hair loss/lack of hair growth/damaged looking hair

Other very rare skin reactions that may occur are:

- allergic reaction at the site of application
- worsening of condition
- application site irritation/pain
- redness
- rash or hives
- if you have psoriasis you may get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis
- skin infection
- acne

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
- increased levels of sugar in your blood or urine
- high blood pressure
- cloudy lens in the eye (cataract)
- increased pressure in the eye (glaucoma)
- vision problems caused by detachment of the retina in the eye (central serous chorioretinopathy)
- 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
- 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. Dermovate Ointment is classed as a very strong 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 Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

**5. How to store Dermovate**

- 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 or carton after (EXP). The expiry date refers to the last day of that month.

- Do not store above 30°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 to protect the environment.

## 6. Contents of the pack and other information

### What Dermovate contains

- The active ingredient is clobetasol propionate. Each 1 g contains 0.5 mg of clobetasol propionate (0.05% w/w).
- The other ingredients are propylene glycol (see section 2), sorbitan sesquioleate and white soft paraffin.

### What Dermovate looks like and contents of the pack

Within each carton is a tube with a plastic screw cap, which contains either 30 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 Limited (Trading as Glaxo Wellcome Operations), Harmire Road, Barnard Castle, DL12 8DT, United Kingdom

Or

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

### 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**      **Dermovate Ointment**

Reference number 10949/0028

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

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