

Reason for Update: Project Pine – Update to Manufacturing Details  
Market: Ireland  
Agency Approval Date:  
Text Date: 16/03/2021  
Text Issue and Draft No.: Issue 15, Draft 1

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

### **Dermovate 0.05% w/w 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.
- In this leaflet, Dermovate 0.05 % w/w Ointment will be called Dermovate.

#### **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 the active substance clobetasol propionate 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).

Dermovate is used to help reduce the redness and itchiness of certain skin problems in adults, the elderly and children over the age of 1 year.

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 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)
- conditions that have not responded to milder steroid creams or ointments.

For children over the age of 1 year, Dermovate 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 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 the age of 1 year.
- to treat any of the following skin problems, it could make them worse:
  - acne
  - rosacea (severe flushing of skin on and around your nose, cheeks, chin, forehead or entire face with or without tiny visible blood vessels, bumps (papules) or pus-filled bumps (pustules))
  - spotty red rash around your mouth (perioral dermatitis)
  - itching around the anus or genitals (penis and 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 have previously had an allergic reaction with another steroid.
- your doctor has directed you to use an airtight dressing, as dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much ointment and the following symptoms may occur; increased weight, moon face/rounding of the face, skin thinning, changes to the colour of your skin, increased body hair, worsening of condition, pustular psoriasis (if you have psoriasis you may get raised bumps with pus under the skin).
- you are applying the cream under an airtight dressing, including a child's nappy, make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.
- you are applying to a large surface area.
- you are applying the cream on broken or damaged skin or within skin folds.
- you have psoriasis, your doctor will want to see you more often.
- 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.
- you are applying to thin skin such as the face, as Dermovate may cause skin thinning. Use on the face should be limited to only a few days.
- you are applying near eyes or eyelids, as cataract (clouding of the eye's lens) or glaucoma may result if the cream repeatedly enters the eye.
- an infection develops during the use of this medicine talk to your doctor or pharmacist.
- 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.

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- 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.

Only use Dermovate for as long as your doctor recommends. If your condition does not improve within 2 to 4 weeks of treatment, speak to your doctor.

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 this medicine on children under the age of 1 year.
- Avoid continuous treatment for a long period of time in infants and children over the age of 1 year with or without an occlusive dressing or nappy as adrenocortical suppression (where the body produces lower levels of the hormone cortisol than normal) and growth retardation may occur.
- Use on children should be limited to a few days and reviewed weekly.

### **Other medicines and Dermovate**

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

Some medicines may affect how Dermovate 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 using 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**.

### **Important information about some of the ingredients of Dermovate**

Dermovate contains 50 mg propylene glycol per gram of product which 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**

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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**

- 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.
- This ointment is for use on your skin only.
- If you are also using an emollient (moisturising) preparation, allow time for Dermovate to soak into your skin before applying the emollient.
- 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 directed to cover the treated area with a dressing always clean the skin before putting on a fresh dressing, 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.
- If your skin problem does not improve in 2 to 4 weeks, talk to your doctor.

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

- 1 Wash your hands.
- 2 Apply the ointment sparingly to the affected area.
- 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.

### **Use in children**

- Do not use this medicine on children under the age of 1 year.
- A course of treatment for an infant or child over the age of 1 year should not be used continuously for a long period of time as adrenocortical suppression (where the body produces lower levels of the hormone cortisol than normal) may occur. Your doctor may want to see the child every week, whilst using the ointment.
- It is especially important in children not to exceed the prescribed amount.

### **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 have frequently relapsing eczema**

If your eczema flares up frequently, your doctor may suggest that you apply Dermovate less frequently once your eczema is under control, to help stop your eczema from coming back (e.g. you may be advised to apply a thin film of Dermovate once daily, two times a week to areas of skin which have been affected by eczema, or to those areas where it is likely to re-appear).

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### **If you use more Dermovate 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: stretch marks, the appearance of blood vessels under the surface of your skin, 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 you accidentally swallow Dermovate, it could make you ill. Rinse your mouth out with plenty of water and contact your doctor or pharmacist for advice.

### **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 missed doses.

### **If you stop using Dermovate**

If you use Dermovate 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.

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

- you find that your skin problem gets worse, becomes swollen during treatment or you have the following very rare symptoms at the site of application:
  - redness
  - rash
  - itching
  - pale red raised bumps (hives)
  - skin burning
  - contact dermatitis

You may be allergic to the ointment, have an infection or need other treatment.

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

- **Common:** may affect up to 1 in 10 people itchy skin
- local skin burning or pain

**Uncommon:** may affect up to 1 in 100 people

- skin thinning, this may cause stretch marks

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- the appearance of blood vessels under the surface of your skin

**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
- 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.

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### **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 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 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 any 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 Dermovate contains**

- The active substance 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**

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

Not all pack sizes may be marketed.

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

#### **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 March 2022.**

#### **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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