

## Package Leaflet: Information for the User

### **Dermovate® Cream** **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 of the 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 eczema, psoriasis, lichen planus, discoid lupus, 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 old
- 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 back passage or private parts
  - infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
  - 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 Dermovate.

#### **Warning and precautions**

Talk to your doctor or pharmacist before using Dermovate if:

- you have previously had an allergic reaction with another steroid
- 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 skin folds.
- using for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- you are applying to a large surface area 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. Use on children should be limited to 5 days and reviewed weekly. Use on the face should be limited to 5 days.
- dressing or bandages should not be used on children or on the face where the cream is applied.

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

#### **Dermovate Cream contains propylene glycol, cetostearyl alcohol and chlorocresol**

Propylene glycol may cause skin irritation. Cetostearyl alcohol may cause local skin reactions (eg. contact dermatitis). Chlorocresol may cause allergic reactions.

### **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 1 or 2 times a day. This may be reduced as your skin begins to get better, or stopped when 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). If you need treatment for a long time, your doctor may decide you need to use a milder cream or ointment
- The germs that cause infections like warm and moist conditions under dressings so always clean the skin before a fresh dressing is put on.

- 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 in 2 to 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 Dermovate 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.

#### **[Pictogram of 1 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.

### **For an adult**

#### **[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

- Do not use it 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. The doctor may want to see the child every week, whilst using the cream.

#### **If you have psoriasis**

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

#### **If you apply Dermovate to your face**

You should only apply the cream to your face if your doctor tells you to. It should be limited to only 5 days as the skin on your face thins easily. **Do not let the cream 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 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 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 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 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 cream is applied.

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

- Stretch marks may develop.
- Veins under the surface of your skin may become more noticeable.

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

- An increased risk of infection
- An allergic skin reaction where the cream is applied
- Rash, itchy bumpy skin or redness of the skin
- Thinning and dryness of your skin and it may also damage or wrinkle more easily
- An increase or reduction in hair growth or hair loss and changes in skin colour.
- 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 the 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](http://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 Dermovate

- Keep 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 25°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 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 cetostearyl alcohol, glyceryl monostearate, arlacel 165, beeswax substitute 6621, propylene glycol, chlorocresol, sodium citrate, citric acid and purified water.

### 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 cream.

### Marketing Authorisation Holder and Manufacturer

Product licence held by Glaxo Wellcome UK Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT

Manufactured by Glaxo Wellcome Operations, Barnard Castle, Durham DL12 8DT

### 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 Cream**

Reference number   10949/0025

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

**This leaflet was last revised in August 2014.**

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