

Package Leaflet: Information for the User

DERMOVATE® CREAM CLOVATE CREAM (Clobetasol Propionate)

Your medicine is called by the above name but will be referred to as Dermovate throughout the following leaflet.

Read all of this leaflet carefully before you start using this medicine.

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Dermovate is and what it is used for
2. Before you use Dermovate
3. How to use Dermovate
4. Possible side effects
5. How to store Dermovate
6. Further 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 and dermatitis that have not responded to milder steroid creams or ointments.

2. BEFORE YOU USE DERMOVATE

Do not use Dermovate:

- if you are allergic (hypersensitive) to clobetasol propionate or any of the other ingredients of Dermovate (listed in Section 6)
- on a child under 1 years 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 - unless your doctor has told you to do so
 - viral infections, such as cold sores, herpes or chicken pox
 - fungal infections, such as ringworm, athlete's foot or thrush
 - skin blisters or sores that are caused by an infection.

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.

Take special care with Dermovate

Check with your doctor or pharmacist before using your medicine if:

- 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.

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

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before using this medicine if you are pregnant, might become pregnant or are breast-feeding.

3. HOW TO USE DERMOVATE

Always use Dermovate exactly as your doctor has told you. You should 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 Gently rub the correct amount of cream into the skin until it has all disappeared. You can measure how much Dermovate to use with your fingertip. This picture shows one fingertip unit.



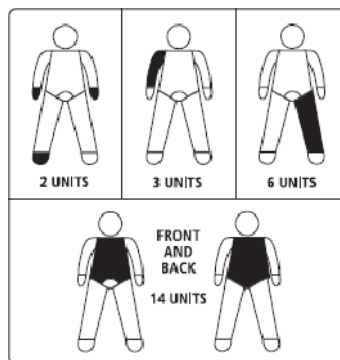
3 Unless you are meant to apply the cream to your hands as a part of the treatment, wash them again after using the cream.

For an adult

You should find that:

- two fingertips of cream will cover both hands or one foot
- three fingertips of cream will cover one arm
- six fingertips of cream will cover one leg
- fourteen fingertips of cream will cover the front and back of the body.

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



For a child

- Do not use it on children under 1 years of age.
- The smaller the child the less you will need to use.
- A child of 4 years needs about a third of the adult 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 not be used for more than 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, by mistake on a few occasions you use more than you should, do not worry. If you apply a lot or if a lot is 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.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dermovate 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 or become 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 Dermovate include:

- A feeling of burning, irritation or itching where the cream is applied.
- If you have psoriasis you may get raised bumps with pus under the skin. This can happen during or after the treatment and is known as pustular psoriasis.

Side effects if you use Dermovate for a long time, or you use a lot each time you apply it, or you apply it under an airtight dressing or a nappy:

- Stretch marks may develop.
- Veins under the surface of your skin may become more noticeable. Increased hair growth and changes in skin colour.
- Thinning of your skin that may also damage more easily.
- Weight gain, rounding of the face and high blood pressure. These are more likely to happen in infants and children.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DERMOVATE

- Do not store above 25°C.
- Keep all medicines out of the sight and reach of children.
- Do not use Dermovate after the expiry date on the tube or carton (Exp). The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION**What Dermovate contains**

- The active ingredient is clobetasol propionate 0.05% w/w.
- The other ingredients are: chlorocresol, cetostearyl alcohol, glyceryl monostearate, Arlacel 165, beeswax substitute 6621, propylene glycol, sodium citrate, citric acid and purified water.

What Dermovate looks like and the contents of the pack

The cream is packed in 30g tubes.

More Information

If you have any questions or are not sure about anything, ask your doctor or pharmacist who will advise you. Other sources of information are:

National Eczema Society, Hill House, Highgate Hill, London N19 5NA
The Psoriasis Association, 2 Queensbridge, Northampton, NN4 7BF

You may also be able to find out more from books in public libraries.

POM PL20507/0109

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CPL/109/3/NOV-07

Leaflet revision date: 8th August 2012