

Package leaflet: Information for the patient

ClobaDerm 0.05% w/w Cream & 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 ClobaDerm is and what it is used for?
2. What you need to know before you use ClobaDerm
3. How to use ClobaDerm
4. Possible side effects
5. How to store ClobaDerm
6. Contents of the pack and other information

1. What ClobaDerm is and what it is used for

ClobaDerm belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.

ClobaDerm 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. What you need to know before you use ClobaDerm

Do not use ClobaDerm:

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

Warnings and precautions:

Talk to your doctor or pharmacist before using ClobaDerm if:

- you are applying the cream or 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 cream or ointment.
- you have psoriasis, your doctor will want to see you more often.

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.

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.

The use of ClobaDerm is not recommended during breast feeding. If you do use ClobaDerm when breast-feeding, do not use it on your breast area to ensure that the baby does not accidentally get /.../ in their mouth.

ClobaDerm Cream contains cetostearyl alcohol which can cause local skin reactions (e.g. contact dermatitis), propylene glycol which may cause skin irritation and chlorocresol which may cause allergic reactions.

/.../ 0.05% w/w Ointment contains propylene glycol which may cause skin irritation.

3. How to use ClobaDerm

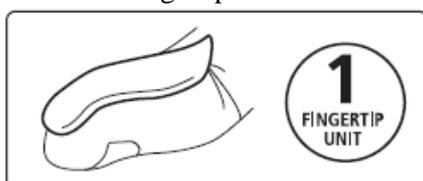
Always use Clobetasol Propionate Cream or Ointment exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Using this medicine

- You usually apply a thin layer of Clobetasol Propionate 1 or 2 times a day. This may be reduced as your skin begins to get better, or stopped when it is better.
- This cream/ointment 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 or 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**, reassessment of the diagnosis, or referral, may be necessary..

Guidance on how to apply the cream or ointment

1. Wash your hands.
1. 2. Gently rub the correct amount of cream or ointment into the skin until it has all disappeared. You can measure how much ClobaDerm to use with your fingertip. This picture shows one fingertip unit.



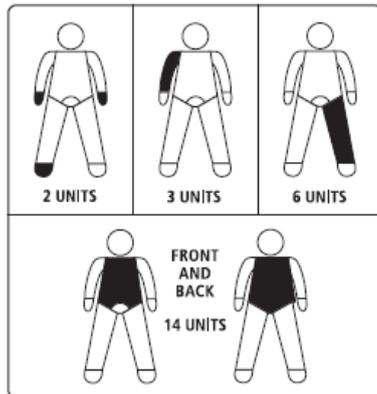
3. Unless you are meant to apply the cream or ointment to your hands as a part of the treatment, wash them again after using the cream or ointment.

For an adult:

You should find that:

- two fingertips of cream or ointment will cover both hands or one foot
- three fingertips of cream or ointment will cover one arm
- six fingertips of cream or ointment will cover one leg
- fourteen fingertips of cream or ointment 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:

- **Children below 1 year:** ClobaDerm is contraindicated in children below 1 year 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.
- Children are more susceptible to local and systemic adverse events caused by topical corticosteroids, and should generally be treated for a shorter duration and with less potent substances than adults. Clobetasol should be used with caution in children, to ensure that the smallest possible dose is applied within the therapeutic range.
- 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. Do not use the cream or ointment under an airtight dressing. The doctor may want to see the child every week, whilst using the cream or ointment.

If you have psoriasis

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

If you apply /.../ to your face

You should only apply the cream or ointment to your face if your doctor tells you to. It should not be used for more than 5 days, and should not be used under a dressing as the skin on your face thins easily. **Do not let the cream or ointment get into your eyes.** If it does, wash it out with plenty of water.

If you use more /.../ 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 ClobaDerm

If you forget to apply your cream or 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.

If you stop using ClobaDerm

If you use ClobaDerm 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, this medicine can cause side effects, although not everybody gets them.

Stop using ClobaDerm and tell your doctor as soon as possible if:

- you find that your skin problem gets worse or your skin becomes swollen during treatment. You may be allergic to the cream or ointment, have an infection or need other treatment.

Other side effects you may notice when using ClobaDerm include:

- A feeling of burning, irritation or itching where the cream or ointment 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.
- Blurred vision (frequency cannot be estimated from the available data).

Side effects if you use ClobaDerm 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 children.

If any of the above side effects are troublesome or last more than a few days or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ClobaDerm

Keep this medicine out of the sight and reach of children.

Do not store above 30 °C.

Do not use this medicine after the expiry date which is stated on the carton and the tube after (MM/YYYY). The expiry date refers to the last day of that month.

This medicine should be disposed of 3 months after first opening.

Do not use the cream or ointment if any visible signs of deterioration, such as noticeable changes in colour, are observed. If you are not sure please check with your pharmacist.

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 ClobaDerm 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:

ClobaDerm Cream: cetostearyl alcohol, glycerol monostearate, arlancel 165 (glycerol monostearate & macrogol 100 stearate), white beeswax, propylene glycol, chlorocresol, sodium citrate, citric acid monohydrate and purified water.

ClobaDerm Ointment: propylene glycol, sorbitan sesquioleate and white soft paraffin.

What /.../ looks like and contents of the pack:

ClobaDerm Cream is a white or almost white cream.

ClobaDerm Ointment is an opaque ointment.

Within each carton is a tube with a plastic screw cap, which contains either 30 or 100 g of cream or ointment.

Not all pack sizes may be marketed.

Marketing authorisation holder

Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

Manufacturer

Tiofarma B.V.
Benjamin Franklinstraat 7-9
3261 LW Oud-Beijerland
The Netherlands

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