TevaArt Ref: PID: 253491_s1 P: Clobetasone Butyrate UK Ointment 0.05% w/w 30g 100g 1 TIO | Version: 5 06 January 2026

UK & Ireland Artwork Department

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- 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 eye (glaucoma)
- increased blood sugar levels or sugar in the urine
- high blood pressure

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.

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 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 Clobetasone Butyrate Ointment

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

Store in the original package in order to protect from light.

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.

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

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 Clobetasone Butyrate Ointment contains
- The active substance is clobetasone butyrate.
  Each 1 g contains 0.5 mg of Clobetasone butyrate (0.05% w/w).
- The other ingredients are liquid paraffin and white soft paraffin.

What Clobetasone Butyrate Ointment looks like and contents of the pack
Clobetasone Butyrate is an opaque ointment.

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Teva UK Limited,
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Manufacturer
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PL 00289/2324

Package leaflet: Information for the user

Clobetasone Butyrate 0.05% w/w Ointment

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

1. What is Clobetasone Butyrate Ointment and what is it used for

Clobetasone Butyrate Ointment contains the active ingredient clobetasone butyrate. This belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.

Clobetasone Butyrate Ointment is used to help reduce the redness and itchiness of certain skin problems. It is used for mild skin problems or to keep your skin problems under control. These skin problems include eczema, dermatitis, nappy rash or insect bites. It is also used to help reduce inflammation of the outer ear.

2. What you need to know before you use Clobetasone Butyrate Ointment

Do not use Clobetasone Butyrate Ointment:
- if you are allergic to clobetasone butyrate or any of the other ingredients of this medicine (listed in Section 6)
- to treat any of the following skin problems, it could make them worse:
  - infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
  - acne
  - severe flushing of skin on and around your nose (rosacea)
  - itchy skin which is not inflamed

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 Clobetasone Butyrate.

Warnings and precautions
Talk to your doctor or pharmacist before using Clobetasone Butyrate if:
- you have previously had an allergic reaction with another steroid
- using for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection
- you have been advised by your doctor to use this medicine under an occlusive dressing (including a child's nappy). Make sure that the skin is cleansed before a fresh dressing is applied to prevent infections. Occlusive dressings (including a child's nappy) make it easier for the active ingredient to pass through the skin, making is possible to accidentally use too much.
- you are applying to thin skin such as the face, as skin is thinner and may absorb larger amounts. Dressings or bandages should not be used on the face where the ointment is applied.
- you are applying to the face over a long period of time as it may cause skin thinning
- you are applying the cream on broken skin 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 experience blurred vision or other visual disturbances
- you accidently swallow a large amount of Clobetasone Butyrate, rinse the mouth out with plenty of water and contact a doctor or pharmacist for advice immediately
- an infection develops (see section 4, Possible side effects).

Children
- Treatment in children under 12 years of age should not normally exceed 7 days.
- Prolonged daily treatment in children can affect their growth. Continuous daily treatment for longer than 4 weeks is not recommended.

continued overleaf

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

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings 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.

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 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.

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. Clobetasone Butyrate is classed as a moderately potent corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

Other medicines and Clobetasone Butyrate Ointment
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Taking some medicines together can be harmful.

In particular, tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines:
- Antivirals such as ritonavir which can be used to treat HIV infection
- Antifungals such as itraconazole which can be used to treat fungal infections

If you are unsure of the types of medicines you are taking, ask your doctor or pharmacist.

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.

Driving and using machines
This medicine will not affect your ability to drive or use heavy machinery.

3. How to use Clobetasone Butyrate Ointment

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 Clobetasone Butyrate up to 2 times a day. This may be reduced as your skin begins to get better.
- This 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) – unless your doctor tells you to.
- If you are using an emollient (moisturising) preparation allow time for Clobetasone Butyrate to be absorbed after each application before applying the emollient.
- 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 after 4 weeks, talk to your doctor.

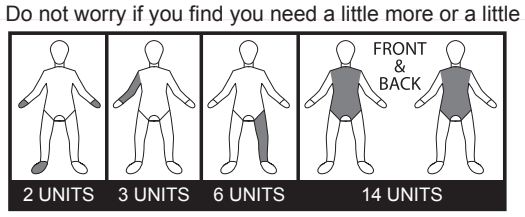
Guidance on how to apply the ointment
1. Wash your hands.
2. Apply a thin layer to the affected area(s) and gently rub into the skin until it has all disappeared. You can measure how much Clobetasone Butyrate to use with your fingertip. For children you will need to use less ointment but still use an adult finger to measure out the fingertip unit. This picture shows one fingertip unit.



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 an adult:
You should find that:
- two and a half fingertips of ointment will cover face and neck
- two fingertips of ointment will cover both hands or one foot
- three fingertips of ointment will cover one arm (not including the hand)
- one fingertip for both sides of the hand
- six fingertips of ointment will cover one leg (not including the foot)
- fourteen fingertips of 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:

Number of fingertip units needed					
Child's age	**Face and neck**	**Arm and hand**	**Leg and foot**	**Front**	**Back including buttocks**
3-6 months	1	1	1 ½	1	1 ½
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 on children younger than 12 years unless advised by a doctor.
- If the condition worsens or does not improve within 7 days, consult a doctor.
- Once the condition improves, reduce both the amount applied and the frequency of application to the minimum necessary to relieve symptoms.
- Do not use every day for mote than 4 weeks at a time.

If you apply Clobetasone Butyrate Ointment to your face
You should only apply the ointment to your face if your doctor tells you to. The ointment should not be used for too long as the skin on your face thins easily. Do not let the ointment get into your eyes. If it does, wash it out with plenty of water.

If you use more Clobetasone Butyrate Ointment than you should
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 Clobetasone Butyrate Ointment
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.

If you stop using Clobetasone Butyrate Ointment
If you use Clobetasone Butyrate 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 Clobetasone Butyrate Ointment and tell your doctor as soon as possible if
- you find that your skin condition 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.

Other side effects you may notice when using Clobetasone Butyrate include

Very rare (may affect up to 1 in 10,000 people)
- an increased risk of skin infection
- an allergic skin reaction where the ointment is applied
- a feeling of burning, irritation or itching where the ointment is applied
- rash, itchy bumpy skin or redness of the skin
- increased hair growth and changes in skin colour
- thinning of your skin and it may also damage more easily
- weight gain, rounding of the face

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