

Package leaflet: Information for the user

Clobavate 0.05% w/w Ointment

Clobetasone Butyrate

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 Clobavate and what is it used for
2. What you need to know before you use Clobavate
3. How to use Clobavate
4. Possible side effects
5. How to store Clobavate
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1. What is Clobavate and what is it used for

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

Clobavate 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 or insect bites. It is also used to help reduce inflammation of the outer ear.

2. What you need to know before you use Clobavate

Do not use Clobavate:

- if you are allergic (hypersensitive) 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:
 - 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
 - itchy skin which is not inflamed
- if a dressing is applied to a child under one year of age
- if you suffer from skin conditions such as acne, rosacea (redness of the face) and perioral dermatitis (tiny red bumps around the mouth)

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 Clobavate.

Warnings and precautions

Talk to your doctor or pharmacist before using Clobavate

- if you have previously had an allergic reaction with another steroid
- if using for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection
- if you are applying the 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 ointment
- if you have psoriasis, your doctor will want to see you more often
- if you are applying the ointment on broken skin or within the skin folds
- if you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the ointment repeatedly enters the eye
- if 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
- if dressing or bandages should not be used on children or on the face where the ointment is applied
- if you are applying to the face over a long period of time as it may cause skin thinning

- if use on children should be limited to 7 days
- if you accidentally swallow. Rinse the mouth out with plenty of water and contact a doctor or pharmacist for advice immediately

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.

Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and Clobavate

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 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 taking this medicine.

Driving and using machines

This medicine will not affect your ability to drive or use heavy machinery.

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 cream/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.

3. How to use Clobavate

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 Clobavate 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 Clobavate 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, talk to your doctor.

Guidance on how to apply the ointment

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



This picture shows one fingertip unit.

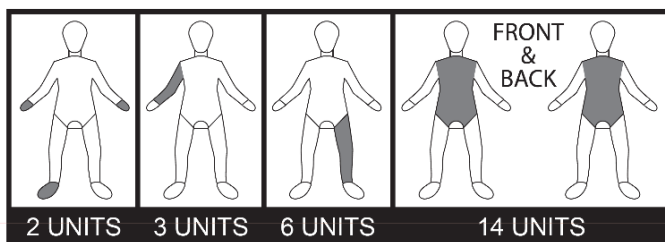
3. Unless you are meant to apply the ointment to your hands as a part of the treatment, wash them again after using the ointment.

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:

- 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 7 days - unless your doctor has told you to use it for longer.

If you apply Clobavate 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 Clobavate 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 Clobavate

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 Clobavate

If you use Clobavate 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 Clobavate 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 ointment, have an infection or need other treatment.
- 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.

Other side effects you may notice when using Clobavate include

Uncommon (may affect up to 1 in 100 people):

- Blurred vision

Very rare (may affect up to 1 in 10,000 people):

- An increased risk of skin infection
- An allergic skin reaction where the cream is applied
- A feeling of burning, irritation or itching where the ointment is applied
- Rash, itchy bumpy skin or redness of the skin

Other very rare side effects if you use Clobavate 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:

- Increased hair growth, increased appetite 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
- Delayed weight gain or slowing of growth in children

continued overleaf

- 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
- Changes in the normal menstrual cycle for women

Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on 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 Clobavate

Keep this medicines 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 Clobavate 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 Clobavate looks like and contents of the pack

Clobavate 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

Marketing Authorisation Holder

TEVA UK Limited, Eastbourne,
BN22 9AG, UK

Manufacturer:

Tiofarma B.V.
Benjamin Franklinstraat 5-10
3261 LW Oud-Beijerland
The Netherlands

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