

## **PACKAGE LEAFLET**

### **Patient Information Leaflet**

#### **Clobavate 0.05% w/w Ointment (Clobetasone Butyrate)**

**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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What is Clobavate and what is it used for?
2. Before you use Clobavate
3. How to use Clobavate
4. Possible side effects
5. Storing Clobavate
6. Further information

### **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. Before you use Clobavate**

#### **Do not use Clobavate:**

- if you are allergic (hypersensitive) to clobetasone butyrate or any of the other ingredients of Clobavate (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:**

Check with your doctor, pharmacist before using Clobavate 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 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.
- you have psoriasis, your doctor will want to see you more often.
- you are applying the ointment on broken skin or within the skin folds.
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the ointment 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.
- dressing or bandages should not be used on children or 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.
- use on children should be limited to 7 days.
- 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.

### **Other medicines and Clobavate:**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. 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:**

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

### **Driving and using machines:**

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

## **3. How to use Clobavate**

Always use Clobavate exactly as your doctor or pharmacist has told you. You should 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.

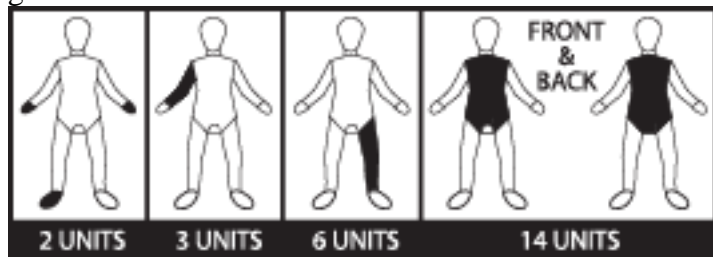
3. Unless you are meant to apply the ointment to your hands as a part of the treatment, wash them again after using the ointment.

### **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 product, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, Clobavate 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:**

##### **Very rare (affects less than 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
- 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.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see below). By reporting side effects you can help provide more information on the safety of this medicine.

### **United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

### **Ireland**

HPRA Pharmacovigilance,  
Earlsfort Terrace, IRL – Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie)

E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

## **5. Storing Clobavate**

Keep all medicines out of the reach and sight of children.

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

Do not use the Clobavate after the expiry date (Exp xx/yyyy) which is shown on the tube or carton. The expiry date refers to the last day of that month.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. This will help to protect the environment.

## **6. Further Information**

### **What Clobavate contains:**

The active ingredient 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:**

Auden Mckenzie (Pharma Division) Ltd.

Mckenzie House

Bury Street

Ruislip

Middlesex

HA4 7TL

UK

**Manufacturer:**

Tiofarma B.V.

Benjamin Franklinstraat 7-9

3261 LW Oud-Beijerland

The Netherlands

**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.

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

**For information in large print, on tape, on CD or in Braille, phone +44 (0)1895 627 420.**