

## Trimovate Cream

clobetasone 17-butyrate, calcium oxytetracycline and nystatin

### PACKAGE LEAFLET: INFORMATION FOR THE USER

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

#### 1 What Trimovate is and what it is used for

Trimovate contains three different active substances called clobetasone butyrate, calcium oxytetracycline and nystatin.

Clobetasone butyrate belongs to a group of medicines called corticosteroids. It helps to reduce redness, swelling and irritation of the skin.

Calcium oxytetracycline (an antibiotic) and nystatin (an antifungal) are medicines used to fight infections. They fight certain bacterial and fungal infections of the skin.

Trimovate is used in adults, the elderly, children and infants to help reduce the redness and itchiness of certain skin problems, such as eczema, nappy rash and dermatitis where infection may be a problem.

#### 2 What you need to know before you use Trimovate

##### Do not use Trimovate:

- if you are allergic to clobetasone butyrate, calcium oxytetracycline or oxytetracycline, nystatin or any of the other ingredients of this medicine (listed in section 6)
- to treat any of the following skin problems, as it could make them worse:
  - acne
  - fungal or bacterial infections such as ringworm, athlete's foot, thrush, or impetigo
  - viral infections, such as cold sores, herpes or chicken pox
  - rosacea (a facial skin condition where the nose, cheeks, chin, forehead or entire face are unusually red, with or without tiny visible blood vessels, bumps (papules) or pus-filled bumps (pustules))
  - itchy skin which is not inflamed
  - to treat perioral dermatitis

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Trimovate. Some bacterial infections may not fully respond to treatment with Trimovate.

**If your infection worsens at any time, speak to your doctor straight away.**

#### Warnings and precautions

Talk to your doctor or pharmacist before using Trimovate.

- Check with your doctor or pharmacist if you are applying the cream under a child's nappy or an airtight dressing. Nappies and airtight dressings make it easier for the active ingredient to pass through the skin and it is possible to accidentally end up using too much cream. Only use an airtight dressing over this medicine if your doctor has told you to. If you are applying Trimovate under an airtight dressing, including a child's nappy, make sure that the skin is cleansed before a fresh dressing is applied, to prevent infections
- Antibiotics may cause a condition that can result in severe diarrhoea and stomach cramps. Although this is unlikely to happen with antibiotics applied to the skin, if you develop stomach cramps or diarrhoea that does not improve or is severe, stop using Trimovate and contact your doctor immediately
- Trimovate may cause slight staining of hair, skin or fabric, but this can be removed by washing. The application may be covered with a non-airtight dressing e.g. cotton bandage or clean cloth to protect clothing

- Trimovate can cause increased sensitivity to sunlight. Avoid using sunlamps and spending a long time in the sun while using Trimovate and use a sunscreen product and protective clothing to prevent sunburn
- Take care when applying Trimovate to the eyelids to make sure it does not accidentally get into your eye
- If you accidentally get Trimovate in your eyes wash them well with water
- Contact your doctor if you experience blurred vision or other visual disturbances
- Take care when applying Trimovate to the face over a long period of time as it may cause skin thinning
- If you have eczema around a leg ulcer, using Trimovate may increase the risk of an allergic reaction or an infection around the ulcer
- Only use Trimovate for as long as your doctor recommends
- **If your condition does not improve after 7 days of treatment, speak to your doctor.**
- 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 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.

#### Other medicines and Trimovate

Some medicines may affect how Trimovate works or make it more likely that you'll have side effects.

Examples of these medicines include:

- ritonavir (used to treat HIV infection)
- itraconazole (used to treat fungal infections)

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

#### 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. If you do use Trimovate when breast-feeding, do not use it near your nipple to ensure that the baby does not accidentally get it in their mouth.

#### Trimovate contains cetostearyl alcohol and chlorocresol

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Chlorocresol may cause allergic reactions.

#### 3 How to use Trimovate

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

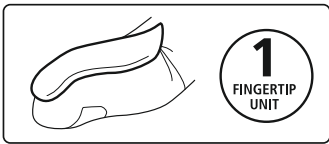
#### Using this medicine

- You usually apply Trimovate once or twice a day.
- This cream is for use on your skin only.
- Do not use more than the amount prescribed for you.
- 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.
- The germs that cause infections like warm, moist conditions under bandages or 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.
- Do not dilute or mix with any other creams or ointments.

#### Guidance on how to apply the cream

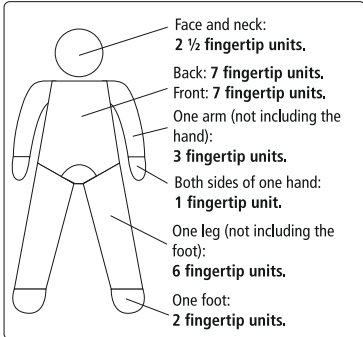
- 1 Wash your hands.
- 2 Apply a thin layer to the affected area(s) and gently rub into the skin until it has all disappeared. You can measure how much Trimovate to use with your fingertip. For children you will need to use less cream but still use an adult finger to measure out the fingertip unit. This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

Ennogen



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

#### For an adult



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

#### For a child

Childs age	Number of fingertip units needed				
	Face and neck	Arm and hand	Leg and foot	Front	Back including buttocks
3-6 months	1	1	1.5	1	1.5
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

#### If you apply Trimovate to your face

You should only apply the cream to your face if your doctor tells you to. The cream should not be used for too long as the skin on your face thins easily. Do not let the cream get into your eyes.

#### If you use more Trimovate 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 the hospital as soon as possible.

#### If you forget to use Trimovate

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 Trimovate

If you use Trimovate regularly make sure you talk to your doctor before you stop using it.

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 Trimovate and tell your doctor immediately if:

- you notice swelling of the face, lips, tongue or other parts of the body, or you have difficulty breathing.
- you find your skin condition gets worse or your skin becomes swollen during treatment. You may be allergic to the cream or need other treatment.

**Side effects with frequencies that cannot be estimated from the available data include:**

**Use over a long period of time, or use under an airtight dressing, may cause the following symptoms:**

- increased weight
- obesity, especially around the centre of the body, moon face / rounding of the face
- skin thinning
- changes to the colour of your skin
- increased body hair

#### Other skin reactions that may occur are:

- allergic reaction at the site of application
- sensitivity to sunlight
- itching
- local skin burning, or pain
- redness
- rash or hives
- worsening of condition
- skin infection
- small, widened blood vessels on the skin

#### The following side effects may also occur in children:

- delayed weight gain
- slow growth

**Side effects that may show up in blood tests or when your doctor gives you a medical examination:**

- a decrease in the level of the hormone cortisol in your blood
- increased levels of sugar in your blood or urine
- high blood pressure
- cloudy lens in the eye (cataract)
- increased pressure in the eye (glaucoma)
- weakening of the bones through gradual loss of minerals (osteoporosis) - additional tests may be needed after your medical examination to confirm if you have this condition

#### Another side effect with an unknown frequency is:

- blurred vision or other visual disturbances

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 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](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5 How to store Trimovate

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the tube end or carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- 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 Trimovate contains

The active substances are clobetasone 17-butyrate, calcium oxytetracycline and nystatin. Each 1 g contains 0.5 mg of clobetasone butyrate (0.05 % w/w), 30 mg oxytetracycline (3 % w/w) as calcium oxytetracycline and 100,000 units of nystatin.

The other ingredients are titanium dioxide, glyceryl monostearate, cetostearyl alcohol, soft paraffin white, polyoxyl 40 stearate, dimeticon 20, glycerol, chlorocresol, sodium metabisulphite, sodium acid phosphate, disodium hydrogen phosphate and purified water.

##### What Trimovate looks like and contents of the pack

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

##### Marketing Authorisation Holder

Ennogen IP Ltd, Unit G4, Riverside Industrial Estate, Riverside Way, Dartford, DA1 5BS, UK.

##### Manufacturer

Ennogen Healthcare Ltd  
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##### Alternative Manufacturer

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