# EUMOVATE

## **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

## 1. Why am I using EUMOVATE?

EUMOVATE contains the active ingredient clobetasone butyrate. EUMOVATE is used to treat eczema and dermatitis.

For more information, see Section <u>1. Why am I using EUMOVATE?</u> in the full CMI.

### 2. What should I know before I use EUMOVATE?

Do not use if you have ever had an allergic reaction to clobetasone butyrate, other similar medicines such as hydrocortisone or any of the ingredients listed at the end of the CMI.

## Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use EUMOVATE? in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with EUMOVATE and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

### 4. How do I use EUMOVATE?

- Follow the instructions provided and use EUMOVATE for no more than 7 days
- The minimum amount of EUMOVATE cream should be used for the minimum amount of time

More instructions can be found in Section <u>4. How do I use EUMOVATE?</u> in the full CMI.

## 5. What should I know while using EUMOVATE?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are using EUMOVATE
Things you should not do	<ul> <li>Do not use EUMOVATE for more than 7 days without speaking to your doctor</li> <li>Do not use EUMOVATE on children under the age of 12 unless advised by a doctor</li> <li>Do not use EUMOVATE to treat any other medical conditions other than eczema and dermatitis unless advised by doctor</li> <li>Do not give the cream to anyone else, even if they have similar symptoms to you</li> </ul>
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how EUMOVATE affects you.
Looking after your medicine	Keep EUMOVATE in the tube where the temperature stays below 25°C

For more information, see Section 5. What should I know while using EUMOVATE? in the full CMI.

## 6. Are there any side effects?

Side effects which have been reported include rash, itch, local skin burning, skin thinning, skin bleaching or increased skin pigmentation and hair disorders.

Worsening of eczema or dermatitis symptoms have also been reported.

Using more than the correct amount of cream may cause changes to your skin.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Active ingredient(s): clobetasone butyrate

## **Consumer Medicine Information (CMI)**

This leaflet provides important information about using EUMOVATE. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EUMOVATE.

#### Where to find information in this leaflet:

- 1. Why am I using EUMOVATE?
- 2. What should I know before I use EUMOVATE?
- 3. What if I am taking other medicines?
- 4. How do I use EUMOVATE?
- 5. What should I know while using EUMOVATE?
- 6. Are there any side effects?
- 7. Product details

### 1. Why am I using EUMOVATE?

### EUMOVATE contains the active ingredient clobetasone

**butyrate.** EUMOVATE is a topical corticosteroid. It is used to control inflammation on the skin.

#### EUMOVATE is used to treat eczema and dermatitis.

It can help you to control patches of dry, red, itchy, flaky or inflamed skin caused by eczema and dermatitis. EUMOVATE works to stop the skin's over-reaction to the triggers that cause skin flare ups. It suppresses the inflammation that causes eczema or dermatitis.

The cream base also has moisturising properties.

# 2. What should I know before I use EUMOVATE?

#### Warnings

#### Do not use EUMOVATE if:

- you are allergic to clobetasone butyrate or any of the ingredients listed at the end of this leaflet.
- you are allergic to other similar medicines such as hydrocortisone.
- always check the ingredients to make sure you can use this medicine.
- you are under the age of 12 years except on advice of a doctor.

#### Do not use EUMOVATE on:

- cuts or open wounds
- infected skin
- inflamed skin near ulcers
- delicate skin such as the face, groin, genitals or between the toes

#### Do not use EUMOVATE to treat:

- rosacea (a skin condition on the face where the nose and cheeks are unusually red)
- acne, spots or pimples

- pruritis (itching) with or without a rash
- perioral dermatitis
- untreated bacterial infections such as cellulitis (an infection of the skin), folliculitis (an infection of the hair follicles), furunculosis (boils) or impetigo (blisters)
- fungal infections such as athletes foot or jock itch
- viral infections such as cold sores, chicken pox or shingles
- parasitic infestations such as scabies
- psoriasis unless it is recommended by your doctor
- any other skin conditions unless advised by your doctor

If you are not sure what is causing your skin problem, ask your doctor or pharmacist.

#### Check with your doctor if you:

- have any other medical conditions
- have any kidney or liver problems
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

#### Pregnancy and breastfeeding

Do not use EUMOVATE if you are pregnant or may become pregnant.

Do not use EUMOVATE If you are breastfeeding.

Your doctor or pharmacist will discuss the benefits and risks of using EUMOVATE whilst pregnant or breastfeeding.

#### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do not use other corticosteroids (like hydrocortisone) on the skin while you are using this cream. You would be doubling the dose.

## Some medicines may interfere with EUMOVATE and affect how it works.

- other corticosteroid medicines which may include some eczema creams, asthma inhalers, tablets, injections, nasal sprays and eye or nose drops
- ritonavir, an antiviral medicine used to treat HIV infection
- itraconazole, an antifungal medicine

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EUMOVATE.

## 4. How do I use EUMOVATE?

#### How much to use

- Follow the instructions provided and use EUMOVATE for no more than 7 days
- The minimum amount of EUMOVATE should be used for the minimum amount of time

#### Steps for applying EUMOVATE:

- Wash your hands and dry them thoroughly before and after applying EUMOVATE
- Squeeze out the cream along the top of your index finger (see picture)
- From the crease in your finger, squeeze the cream halfway to your fingertip. This will cover a patch of skin the same size as the palm of your hand.
- Use the fingertip unit as a guide. For smaller areas, use a smaller amount
- EUMOVATE is not meant to treat large areas.
- Gently rub the cream onto the patch of skin you are treating
- Once applied, do not cover the area with anything (e.g. bandages, dressings, gloves, plastic wrap). It can cause more of the medicine to pass through the skin.
- Be especially careful to not get the cream in your eyes.



#### When to use EUMOVATE

• Use the cream twice a day for a maximum of 7 days. Do not use for more than 7 days unless advised by your doctor.

#### If you forget to use EUMOVATE

EUMOVATE should be used regularly at the same time each day. If you forget to use it or you miss an application, use it when you remember.

## Do not try to make up for missed applications by using more of the cream or applying more frequently.

• This may increase the chance of side effects.

#### If you use too much EUMOVATE

If you think that you have used too much EUMOVATE don't worry but try to keep to the fingertip unit.

Using corticosteroids on the skin continuously over many weeks or months can cause skin thinning or permanent damage.

## If you or anyone swallow EUMOVATE you should immediately:

- phone the Poisons Information Centre (by calling 0800 POISON (0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

# 5. What should I know while using EUMOVATE?

#### Things you should do

• Inform any other doctors, pharmacists or dentists who are treating you that you are using EUMOVATE

#### See your doctor if:

- your condition does not improve after 7 days of treatment or it becomes worse
- you experience frequent flare-ups upon stopping treatment
- you experience blurred vision or other visual disturbances
- you become pregnant whilst using this medicine
- the rash/irritation gets better but then comes back. Do not treat the same area of skin more than twice without first speaking with your doctor.

Remind any doctor, dentist or pharmacist [add other health professionals as appropriate] you visit that you are using EUMOVATE.

#### Things you should not do

- Do not use EUMOVATE to treat any other complaints unless your doctor tells you to
- Do not give EUMOVATE to anyone else even if they have the same condition as you

#### Other skin conditions

It is possible that you are treating the wrong skin condition or that your skin may still be reacting to something that it is coming in contact with.

Some of the common triggers are:

- earrings or studs especially gold-plated earrings
- other jewellery
- coins
- watch buckles, metal straps or the metal back of a watch
- metal studs or fastenings on jeans, bras or underwear

All of these may have a metal in them called nickel that is a very common trigger. If you react badly to nickel, all of the triggers in the list could be a problem.

Other common triggers include rubber and pine tree sap, which are used in things we touch every day. You might find triggers:

- In the home: such as plasters, furniture polish, varnishes, rubber gloves or elastic in clothes.
- In substances you use at work: like glues, oils, lubricants or cement.
- In the garden: certain plants and weeds, gardening gloves.

Even if it is not practical to avoid triggers, there are often practical steps you can take to minimise possible irritation.

EUMOVATE is meant to control skin conditions that improve within 7 days of treatment. If you think you need further treatment after that, see a doctor for advice. Do not keep using it.

If your skin gets worse or it does not improve within 7 days, stop using the cream and see your doctor.

If your skin condition clears up in less than 7 days, stop using the cream. Instead, use emollient (moisturising) products to help stop it coming back.

Skin specialists often advise people with eczema or dermatitis to use emollient (or moisturising) skin products, including creams and bath oils, to keep moisture in the skin. This can make your skin more resistant to flare ups. Avoid using soap and heavily scented products. Ask your doctor or pharmacist for further information.

#### Driving or using machines

Be careful before you drive or use any machines or tools until you know how EUMOVATE affects you.

#### Looking after your medicine

 Keep EUMOVATE in the tube where the temperature stays below 25°C

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

#### Keep it where young children cannot reach it.

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

#### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

If your skin gets worse during treatment, you may have a skin infection or a trigger you have not recognized or even an allergy to the cream.

Stop using EUMOVATE and see your doctor as soon as possible.

#### Less serious side effects

Less serious side effects	What to do
<ul> <li>rash</li> <li>itch</li> <li>local skin burning</li> <li>skin thinning</li> <li>skin bleaching or increased skin pigmentation and hair disorders</li> <li>Worsening of eczema or dermatitis symptoms have also been reported.</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.
The following symptoms may occur with use in children:	
delayed weight gain	

slow growth

#### Serious side effects

Serious side effects	What to do
<ul> <li>using more than the correct amount of cream may cause changes to your skin (e.g. a thinning which can lead to more of the active ingredient passing through the skin and affecting other parts of the body)</li> </ul>	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you
Other side effects that may show up in blood tests or when your doctor gives you a medical examination:	notice any of these serious side effects.
<ul> <li>a decrease in the level of the hormone cortisol in your blood</li> <li>high blood pressure</li> <li>cloudy lens in the eye (cataract)</li> <li>increased pressure in the eye (glaucoma)</li> <li>weakening of the bones through gradual loss of mineral (osteoporosis). Additional tests may be needed after your medical examination to confirm if you have this condition</li> <li>increased blood sugar levels</li> <li>glucose in the urine</li> </ul>	
<ul> <li>The following are rare side effects that could occur if you use more than the correct amount of EUMOVATE or for longer than recommended you may experience: <ul> <li>increased weight</li> <li>moon face or rounding of the face</li> <li>obesity</li> <li>changes to the colour of your skin</li> </ul> </li> </ul>	

• increased body hair

#### Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

#### **Reporting side effects**

After you have received medical advice for any side affects you experience, you can report side effects via https://nzphvc.otago.ac.nz/reporting.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

### 7. Product details

This medicine is only available without a doctor's prescription.

#### What EUMOVATE contains

Active ingredient (main ingredient)	clobetasone butyrate (0.05% w/w)
Other ingredients	arlacel 165
(inactive ingredients)	beeswax substitute 6621
	cetostearyl alcohol
	chlorocresol
	citric acid monohydrate
	dimeticone 20
	glycerol
	glyceryl monostearate
	sodium citrate dihydrate
	water - purified
Potential allergens	cetostearyl alcohol
	chlorocresol

## Do not take this medicine if you are allergic to any of these ingredients.

#### What EUMOVATE looks like

EUMOVATE is a smooth white cream for topical use only. It is available in an aluminium tube weighing 30 g.

#### Who distributes EUMOVATE

GlaxoSmithKline NZ Ltd Private Bag 106600 Downtown Auckland 1143 Phone: (09) 367 2900

This leaflet was prepared in August 2023.

© 2023 GSK group of companies or its licensor. Version 11.0