EUMOVATE

Consumer Medicine Information (CMI) summary

The full CMI 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 relieve the symptoms of certain skin conditions.

For more information, see Section 1. Why am I using EUMOVATE? 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?

- Apply a thin layer of EUMOVATE once or twice a day.
- Do not use EUMOVATE every day for more than 4 weeks at a time.

More instructions can be found in Section 4. How do I use EUMOVATE? 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. Tell your doctor if you experience blurred vision or other visual disturbances. Tell your doctor if you notice your condition does not improve after 4 weeks of using EUMOVATE. Tell your doctor if you notice your skin gets worse during treatment.
Things you should not do	 Do not use EUMOVATE to treat any other complaints unless your doctor tells you to. Do not give your medicine to anyone else, even if they have the same condition as you. Whilst using EUMOVATE, do not smoke or go near naked flames due to the risk of severe burns.
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 in a cool dry place 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, hair disorders, worsening of eczema or dermatitis symptoms, increased weight, rounding of the face, obesity, increased body hair, delayed weight gain (in children) and slow growth (in children).

Serious side effects include allergic reaction, high blood pressure, glaucoma, cataract, a decrease in the level of the hormone cortisol in your blood, increased blood sugar levels, glucose in urine and weakening of the bones through gradual loss of mineral.

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.

EUMOVATE

Active ingredient: 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 corticosteroid. Corticosteroids help to reduce redness, swelling and irritation of the skin.

EUMOVATE is used to relieve the symptoms of certain skin conditions.

These include:

- eczema including seborrhoeic eczema (red skin with greasy looking white or yellowish-coloured scales) and a type of skin reaction triggered by exposure to sunlight (photodermatitis)
- skin rash due to allergy or a substance that irritates your skin (irritant and allergic contact dermatitis)
- prurigo nodularis (itchy nodules on the arms or legs)
- inflammation of the outer ear

Children

In children, EUMOVATE is used for skin conditions that have not responded to milder steroid creams.

2. What should I know before I use EUMOVATE?

Warnings

Do not use EUMOVATE if:

- you are allergic to clobetasone butyrate, other similar medicines such as hydrocortisone, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin

Do not use EUMOVATE to treat:

- infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
- acne
- 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

Do not use EUMOVATE on certain areas of the body such as your face (it's OK on the ears and neck), on the groin and genitals and between your toes.

Check with your doctor if you:

- have any other medical conditions.
- 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>. <u>Are there any side effects</u>?

Pregnancy and breastfeeding

Do not use EUMOVATE if you are pregnant or may be pregnant or if you are breastfeeding unless advised by your doctor.

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

If you use EUMOVATE when breastfeeding, don't use EUMOVATE on your breast area to ensure that the baby does not accidentally get EUMOVATE in their mouth.

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.

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

- ritonavir (a medicine for the treatment of HIV)
- itraconazole (a medicine for the treatment of fungal infections)

Do not use other skin medications with corticosteroids in them (such as hydrocortisone) while you are using EUMOVATE. You may be doubling the dose.

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

 Use the smallest amount of EUMOVATE that will cover the affected area. Half a fingertip will cover a patch of skin the same size as the palm of your hand.

How to use EUMOVATE

- Wash your hands and dry them.
- Squeeze out the correct amount of cream onto your index finger.
- Gently rub the cream into the skin area you are treating.
- Wash your hands again (unless it is your hands you are treating).
- Do not cover the treated patch of skin with anything (bandages, dressings, gloves or plastic wrap) unless your doctor tells you to. It can cause more of the medicine to pass through the skin.
- If you are applying EUMOVATE 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.
- If you are using an emollient (moisturising)
 preparation allow time for EUMOVATE to be absorbed
 after each application before applying the emollient.
- Take care when applying EUMOVATE to your eyelids to make sure it does not get into your eye.
- Take care if you have eczema around a leg ulcer, use of a topical corticosteroid may increase the risk of an allergic reaction or an infection around the ulcer.

When and how long to use EUMOVATE

- Use EUMOVATE once or twice a day. Do not use
 EUMOVATE more than 2 times per day.
- As your skin improves, the number of times you may need to use EUMOVATE each day may lessen.
- EUMOVATE should not be used every day for more than 4 weeks at a time.

If you forget to use EUMOVATE

If you forget to use EUMOVATE or miss a dose, use it when you remember.

Do not apply extra EUMOVATE to make up for missed doses.

If you use too much EUMOVATE

If you use too much of the cream, don't worry but try to keep to the fingertip unit. Using corticosteroids on the skin continuously over many weeks or months may cause skin thinning and permanent skin damage.

If you or anyone else swallows EUMOVATE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 0800 POISON or 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

 tell your doctor or pharmacist if, for any reason, you have not used EUMOVATE exactly as prescribed.
 Otherwise, your doctor or pharmacist may think it was not effective and change your treatment unnecessarily.

Call your doctor straight away if you:

- become pregnant while using EUMOVATE.
- experience blurred vision or other visual disturbances.
- notice your condition does not improve after 4 weeks of treatment.
- notice your skin gets worse during treatment. You may have a skin infection or trigger you may not have recognised.

Remind any doctor, dentist or pharmacist 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 your medicine to anyone else, even if they have the same condition as you.
- Whilst using EUMOVATE, do not smoke or go near naked flames due to the risk of severe burns. Fabric (clothing, bedding, dressing 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.

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 until it is time to use it. Keep your medicine in a cool dry place where the temperature stays below 25°C.

Follow the instructions on 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 condition gets worse or your skin becomes swollen during treatment, you may be allergic to the medicine, have an infection or need other treatment. Stop using EUMOVATE and tell your doctor as soon as possible.

Using more than the correct amount of EUMOVATE may cause changes to your skin e.g. thinning or allow the active ingredient to pass through the skin and affect other parts of the body.

This is not a problem if you use the right amount of EUMOVATE and for the correct period of time.

Less serious side effects

Less serious side effects	What to do
Skin and subcutaneous tissue disorders: rash itch local skin burning skin thinning skin bleaching or increased skin pigmentation and hair disorders worsening of eczema or dermatitis symptoms	Speak to your doctor if you have any of these less serious side effects and they worry you.
Metabolism and nutrition disorders:	
 increased weight moon face or rounding of the face obesity increased body hair delayed weight gain (in children) slow growth (in children) 	

Serious side effects

Serious side effects	What to do
Allergic reaction: Some of the symptoms of an allergic reaction may include: o shortness of breath o wheezing or difficulty breathing o swelling of the face, lips, tongue or other parts of the body o rash, itching or hives on the skin	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Side effects that may show up in blood tests and medical examinations

Side effects that may show up in blood tests or medical examinations:	What to do
Eye disorders:	Speak to your
 cloudy lens in the eye (cataract) increased pressure in the eye (glaucoma) 	doctor if you experience any of these side effects.
Vascular disorders:	
high blood pressure	
Metabolism and nutrition disorders:	
 decrease in the level of the hormone cortisol in your blood increased blood sugar levels glucose in the urine 	
Musculoskeletal and connective tissue disorders:	
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.	

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 effects you experience, you can report side effects via https://pophealth.my.site.com/carmreportnz/s/

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 available with a doctor's prescription.

What EUMOVATE contains

Active ingredient	clobetasone butyrate
(main ingredient)	
Other ingredients	glycerol
(inactive ingredients)	glyceryl monostearate
	cetostearyl alcohol
	beeswax substitute 6621 (contains paraffin- see section 5. What should I know while using EUMOVATE?)
	arlacel 165
	dimeticone 20
	chlorocresol
	sodium citrate dihydrate
	citric acid monohydrate
	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 white cream for topical use that is available in a 30 g or 100 g tube (TT50-2625).

Not all pack sizes may be distributed in New Zealand.

Who distributes EUMOVATE

GlaxoSmithKline NZ Ltd Private Bag 106600 Downtown

Auckland 1143 New Zealand

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