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 treat eczema and dermatitis. It can help you to control patches of dry, red, itchy, flaky or inflamed skin caused by eczema and dermatitis.

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?

- Follow the instructions provided on how to use EUMOVATE.
- The minimum amount of EUMOVATE cream should be used for the shortest amount of time. Do not use EUMOVATE for more than 7 days.

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. Contact your doctor if you are concerned about any side effects. Tell your doctor or pharmacist if your rash/irritation gets better but then comes back, or your skin gets worse or does not improve within a week. Do not treat the same patch more than twice without taking advice from your doctor.
Things you should not do	 Do not use EUMOVATE to treat any other complaints unless your doctor or pharmacist tells you to. Do not use EUMOVATE for more than 7 days without speaking to your doctor or pharmacist. Do not give your medicine to anyone else, even if they have the same condition as you.
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. Serious side effects include allergic reaction, infection, high blood pressure, glaucoma, cataract, a decrease in the level of the hormone cortisol in your blood, increased blood sugar levels, weakening of the bones through gradual loss of mineral and glucose in the urine, increased weight, rounding of the face, obesity, increased body hair, delayed weight gain (in children) and slow growth (in children). 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 0.05% w/w cream

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.

EUMOVATE 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, 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 on:

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

Do not use EUMOVATE unless advised by a doctor to treat any conditions other than eczema and dermatitis.

Do not use the cream on the wrong skin conditions. It could make it worse.

Do not use EUMOVATE to treat:

- rosacea (skin condition of the face where the nose and cheeks are unusually red).
- acne, spots or pimples.
- pruritis (itching) without rash.
- perioral dermatitis.
- untreated bacterial infections such as cellulitis (infection of the skin), folliculitis (infection of the hair follicle), furunculosis (boils) or impetigo (blisters).
- fungal infections such as athlete's foot and jock itch.
- viral infections such as cold sores, chicken pox or shingles.
- parasitic infestations such as scabies.
- psoriasis unless recommended by your doctor.

If you have any of these conditions, ask your doctor or pharmacist for advice.

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

Check with your doctor or pharmacist if you:

- have any other medical conditions, particularly kidney or liver 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 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

You should 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 do use EUMOVATE when breastfeeding, do not use EUMOVATE on your breast area to ensure that the baby does not accidentally get EUMOVATE in their mouth.

Children

Do not use EUMOVATE on children under the age of 12 years except on the advice of a doctor.

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:

- other corticosteroid medicines which may include some eczema creams, asthma inhalers, tablets, injections, nasal sprays, and eye or nose drops.
- ritonavir (a medicine for the treatment of HIV).
- itraconazole (a medicine for the treatment of fungal infections).

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

- EUMOVATE is for external use only.
- The minimum amount of EUMOVATE should be used for the shortest amount of time. Do not use EUMOVATE for more than 7 days.
- Squeeze out the cream along the top of your index finger (see picture).
- From the crease in the 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. This cream is not meant to treat large areas.

Half a fingertip will cover a patch of skin the same size as the palm of your hand

How to use EUMOVATE

Adults and children over 12 years of age:

- Wash your hands and dry them.
- Squeeze out the correct amount of cream to cover the affected area on your index finger. The picture above gives you an idea of how much to use.
- Gently rub cream onto the patch of skin you are treating.
- Wash your hands again (unless it is your hands you are treating).
- Don't cover the treated patch of skin with anything (bandages, dressings, gloves or plastic wrap). It can cause more of the medicine to pass through the skin.
- Be careful not to get the cream in your eyes.

Use in children under 12 years of age only on the advice of a doctor.

When to use EUMOVATE

- Use the cream twice a day for up to 7 days.
- Using it at the same time each day will have the best effect. It will also help you remember when to use it.

If you forget to use EUMOVATE

If you forget to use EUMOVATE or miss an application, use it when you remember.

Do not try to make up for missed applications by using the cream more often as this may increase the chance of you getting a side effect.

If you use too much EUMOVATE

If you use a bit too much of the cream by mistake, 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 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 13 11 26), 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

Remind any doctor, dentist or pharmacist you visit that you are using EUMOVATE. See your doctor straight away if:

- you become pregnant while using EUMOVATE.
- you experience blurred vision or other visual disturbances.
- you experience any side effects.
- you notice your rash/ irritation gets better but then comes back. Don't treat the same patch more than twice without taking advice from your doctor.
- you notice your skin gets worse or it does not improve within a week.

Things you should not do

- Do not use EUMOVATE to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not use for more than 7 days except on advice of a doctor.

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

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.

If your skin condition clears up in less than a week, stop using the cream. Think about 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.

Looking after your medicine

Keep your cream in the pack 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 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.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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.

Do not use this medicine if the packaging is torn or shows signs of tampering.

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 recognised or even an allergy to the cream. Stop using EUMOVATE and see a doctor or pharmacist as soon as possible.

Using more than the correct amount of cream 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 cream and for the correct period of time.

Some side effects may show up in blood tests or when your doctor gives you a medical examination.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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 or pharmacist if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do		
Allergic reaction:	Call your doctor		
Symptoms of an allergic reaction include some or all of the following:	straight away, or go straight to the		
 shortness of breath wheezing or difficulty breathing swelling of the face, lips/mouth, tongue, throat or other parts of the body rash, itching, redness, or hives on the skin 	Emergency Department at your nearest hospital if you notice any of these serious side effects.		
Eye disorders:			
 cloudy lens in the eye (cataract) increased pressure in the eye (glaucoma) 			
Vascular disorders:			
high blood pressure			
Infection:			
Symptoms of an infection include some or all of the following:			
heat and or redness at the sitefever			
Metabolism and nutrition disorders:			
 decrease in the level of the hormone cortisol in your blood increased blood sugar levels 			
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.			
Renal and urinary disorders:			
glucose in the urine			

The following are very rare side effects and may occur if you use more than the correct amount of cream or for longer than recommended:

Serious side effects	What to do
 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) 	Contact your doctor if you experience any of these side effects.

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 to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. 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 over-the-counter without a doctor's prescription.

What EUMOVATE contains

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

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 that is available in a 15 g or 30 g tube (AUST R 178288).

A 5 g sample tube is also available from your doctor only.

Not all pack sizes may be distributed in Australia.

Who distributes EUMOVATE

GlaxoSmithKline Australia Pty Ltd Level 4, 436 Johnston Street, Abbotsford, Victoria, 3067

Phone: 1800 033 109

www.gsk.com.au

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This leaflet was prepared on 4 August 2025.

Version 12.0