

EUMOVATE Cream

Clobetasone butyrate 0.05% w/w

New Zealand Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using EUMOVATE Cream.

This leaflet answers some common questions about EUMOVATE Cream. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

EUMOVATE Cream is available with a doctor's prescription from your pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking EUMOVATE Cream against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What EUMOVATE Cream is used for

The name of your medicine is EUMOVATE Cream. EUMOVATE Cream contains clobetasone butyrate which belongs to a group of medicines called corticosteroids.

Corticosteroids help to reduce redness, swelling and irritation of the skin. EUMOVATE Cream relieves the symptoms of certain skin problems.

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)
- inflammation of the outer ear
- prurigo nodularis (itchy nodules on the arms or legs)

For children EUMOVATE Cream is used for dermatitis that has not responded to milder steroid creams.

Before you use EUMOVATE Cream

When you must not use it

Do not use EUMOVATE if you have an allergy to:

- any medicine containing clobetasone butyrate
- any of the ingredients listed at the end of this leaflet.
- any other similar medicines such as hydrocortisone.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not use EUMOVATE Cream to treat any of the following skin problems, it could make them worse:

- 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.

If you think any of these apply to you, don't use EUMOVATE Cream until you have checked with your doctor or pharmacist.

Do not use EUMOVATE Cream if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor or pharmacist says you should.

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

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

Do not put the cream in your eyes. If you need to apply EUMOVATE Cream to your eyelid, do so carefully.

Do not apply EUMOVATE Cream after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If you apply it after the expiry date has passed, it may not work as well.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you become pregnant or are planning to become pregnant or are breastfeeding.

Your doctor will discuss the possible risks and benefits of using EUMOVATE Cream during pregnancy or breastfeeding.

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

Taking other medicines

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

Some medicines and EUMOVATE Cream may interfere with each other. 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 this cream. You would be doubling the dose.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use EUMOVATE Cream

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

EUMOVATE Cream is for external use only.

How much to use

Use only enough EUMOVATE Cream to 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 it

Use EUMOVATE Cream once or twice a day.

The number of times you use your medicine may be reduced as your skin gets better.

- Wash your hands and dry them
- Squeeze out the correct amount of cream onto your index finger. Half a fingertip will cover a patch of skin the same size as the palm of your hand.
- Gently rub the cream into the skin area you are treating.
- Wash your hands again (unless it is your hands you are treating).
- If you are using an emollient (moisturising) preparation allow time for EUMOVATE Cream to be absorbed after each application before applying the emollient.

How long to use it

Do not use EUMOVATE Cream more than 2 times per day.

Only use EUMOVATE Cream for as long as your doctor recommends.

This medicine should not be used every day for more than 4 weeks at a time.

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

If your condition does not improve after 4 weeks of treatment, speak to your doctor.

If you forget to use it

If you forget to use it or miss a dose don't worry, use it when you remember. Do not apply extra EUMOVATE Cream to make up for missed doses.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you use too much of the cream, don't worry-but try to keep to the fingertip unit.

If you or anyone swallow a large amount of EUMOVATE Cream, rinse your mouth out with plenty of water and immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using EUMOVATE Cream

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using EUMOVATE Cream.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you experience blurred vision or other visual disturbances, speak to your doctor.

Take care when applying EUMOVATE Cream to the eyelids

to make sure it does not get into your eye.

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.

Tell your doctor or pharmacist if, for any reason, you have not used EUMOVATE Cream exactly as prescribed.

Otherwise, your doctor or pharmacist may think it was not effective and change your treatment unnecessarily.

If your skin gets worse during treatment, you may have a skin infection or a trigger you may not have recognised. See your doctor or pharmacist for advice.

Things you must not do

Do not use EUMOVATE Cream 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.

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 Cream 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.

Side-Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using EUMOVATE Cream.

Like other medicines, EUMOVATE Cream can cause some side-effects although not everybody gets them. If they occur, they are most likely to be minor and temporary.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following:

- rash
- itch
- local skin burning
- skin thinning
- skin bleaching or increased skin pigmentation and hair disorders

Worsening of eczema or dermatitis symptoms has also been reported.

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.

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:

If you use more than the correct amount of cream or for longer than recommended you may experience:

- increased weight moon face or rounding of the face
- obesity
- changes to the colour of your skin
- increased body hair

The following symptoms may occur with use in children:

- delayed weight gain
- slow growth

Other 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
- high blood pressure
- cloudy lens in the eye (cataract)

- increased pressure in the eye (glaucoma)
- 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.

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 Cream and tell your doctor as soon as possible.

Other side effects not listed above may also occur in some people.

After using EUMOVATE Cream

Storage

Keep EUMOVATE Cream in a cool dry place where the temperature stays below 25°C.

Do not store EUMOVATE Cream or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If you stop taking EUMOVATE Cream, or it has passed the expiry date, ask your pharmacist what to do with any cream left over.

Product Description

What EUMOVATE Cream looks like

EUMOVATE Cream contains 0.05% clobetasone butyrate BP. It is white in appearance. It is packaged in an aluminium tube with a polypropylene cap.

Ingredients

EUMOVATE Cream also contains the following:

- Glycerol
- Glycerol monostearate
- Cetostearyl alcohol
- Beeswax substitute 6621
- Arlcel 165
- Dimethicone 20
- Chlorocresol
- Sodium citrate
- Citric acid monohydrate
- Purified water

Supplier

EUMOVATE Cream is supplied by:

GlaxoSmithKline New Zealand
Limited
Private Bag 106600
Downtown, Auckland

Further information

Pharmaceutical companies are not in a position to give people individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

**Do not throw this leaflet away.
You may need to read it again.**

This leaflet was prepared 19
September 2018.

The information provided applies
only to EUMOVATE Cream.

Trade marks are owned by or licensed to the GSK group of companies.

© 2018 GSK group of companies or its licensor.

This leaflet is copyrighted to GlaxoSmithKline and may be reproduced but not altered in any way.

Version 5.0