

BETNOVATE™

Betamethasone Valerate 0.122% w/w Lotion BP

New Zealand Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you use BETNOVATE.

This leaflet answers some common questions about BETNOVATE. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you using BETNOVATE against the risks this medicine could have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What is BETNOVATE used for?

BETNOVATE is used to treat various inflammatory skin conditions, including eczema, psoriasis, dermatitis, insect bites and prickly heat.

BETNOVATE belongs to a group of medicines known as corticosteroids, frequently called 'steroids'. They are not 'anabolic steroids' which are the steroids sometimes misused by athletes.

BETNOVATE works by reducing the inflammation in the affected area to reduce the redness, swelling and itchiness of the skin.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed BETNOVATE for another reason.

BETNOVATE is not addictive.

This medicine is available only with a doctor's prescription.

Before you use BETNOVATE

When you must not use it

Do not use BETNOVATE if you have an allergy to:

- any medicine containing betamethasone valerate or any of the ingredients listed toward the end of this leaflet.
- any other similar medicines such as other corticosteroids

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 BETNOVATE on children under 1 year of age.

Do not use BETNOVATE if you already have an infection unless your doctor tells you to.

You may need to use additional medicine.

Do not use BETNOVATE 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))
- rashes around the mouth
- itchy skin which is not inflamed
- itching around the anus or genitals (penis and vagina)

If you think any of these apply to you, do not use BETNOVATE until you have checked with your doctor or pharmacist.

Do not let BETNOVATE lotion get in your eyes.

Do not use BETNOVATE after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

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

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you do use BETNOVATE when breast-feeding, do not use on your breast area so that the baby does not accidentally get BETNOVATE in their mouth.

If you have not told your doctor about any of the above, tell him/her before you start taking BETNOVATE.

Taking other medicines

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

Some medicines and BETNOVATE may interfere with each other. These include:

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

These medicines may be affected by BETNOVATE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to use BETNOVATE?

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 in this leaflet, ask your doctor or pharmacist for help.

Due to the flammable nature of BETNOVATE, you should

avoid smoking or being near an open flame while you're applying BETNOVATE, and immediately after you've used it.

How much to use

Use only enough BETNOVATE to cover the entire affected area once or twice a day.

The number of times you use BETNOVATE may be reduced as your skin gets better or your doctor may prescribe a weaker steroid for you to use instead.

How to use it

Apply a thin layer once or twice daily and gently rub in, using only enough to cover the entire affected area.

Wash your hands after use unless treating the hands.

If you are also using an emollient (moisturising) preparation allow time for BETNOVATE to be absorbed after each application before applying the emollient.

If your eczema flares up frequently, your doctor may suggest that you use a less frequent dose of BETNOVATE once your eczema is under control, to help stop your eczema from coming back.

When to use it

Use BETNOVATE at about the same time each day.

Using it at the same time each day will have the best effect. It will also help you remember when to use it.

How long to use it for

BETNOVATE should be used once or twice daily for no more than four weeks at a time.

Only use BETNOVATE for as long as your doctor recommends. If the condition worsens or does not improve within two to four weeks, talk to your doctor or pharmacist.

If you forget to use BETNOVATE

If you forget to use BETNOVATE apply it as soon as you remember then continue as before.

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

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

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

Don't stop using BETNOVATE without advice

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to the Accident and Emergency Department at your nearest hospital, if you think you or anyone else may have taken too much BETNOVATE, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are using BETNOVATE

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

If you are about to be started on any new medicine, remind your

doctor and pharmacist that you are using BETNOVATE.

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

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

Things you must not do

Do not use BETNOVATE on children under 1 year of age.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use BETNOVATE to treat any other complaints unless your doctor tells you to.

Do not let BETNOVATE get into your eyes.

Things to be careful of

Take care when applying BETNOVATE to the eyelids to make sure it does not get into your eye.

Take care when applying BETNOVATE to the face over a long period of time as it may cause skin thinning.

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.

Only use an airtight dressing over this medicine if your doctor has told you to.

If you are applying BETNOVATE under an airtight dressing, make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.

Be careful driving or operating machinery until you know how BETNOVATE affects you.

What are the side effects?

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

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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 and they worry you:

- skin rash
- hot or burning sensation
- itching

Tell your doctor as soon as possible if you notice any of the following:

- thinning of the skin and appearance of stretch marks
- changes to the colour of your skin
- increase in hair growth
- appearance of blood vessels under the surface of your skin

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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.
- wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These

could be a symptom of an allergic reaction.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

- increased weight
- moon face / rounding of the face
- obesity
- skin thinning, this may cause stretch marks
- skin wrinkling
- skin dryness
- the appearance of blood vessels under the surface of your skin
- increased body hair
- hair loss / lack of hair growth / damaged looking hair

Other very rare skin reactions that may occur are:

- allergic reaction at the site of application
- worsening of condition
- application site irritation
- redness
- rash or hives
- If you have psoriasis you may get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.
- skin infection.

Very rare side effects that may show up in blood tests or when your doctor gives you a medical examination:

- 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 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 that is making you feel unwell.

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

After using BETNOVATE

Storage

Keep BETNOVATE in its bottle until time to use it.

Keep this medicine where children cannot reach it.

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

Keep BETNOVATE in a cool, dry place where it stays below 25°C.

Keep the bottle tightly closed when not in use. Contents are flammable.

Keep BETNOVATE out of direct sunlight.

Do not store BETNOVATE or any other medicines in the bathroom or near a sink. Do not leave it in a car or on a window sill.

Heat and dampness can destroy some medicines.

Discard 3 months after opening.

Disposal

If your doctor tells you to stop taking this medicine or the

expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What BETNOVATE looks like

BETNOVATE lotion is supplied in 50 mL bottles. It is a white, translucent lotion.

Ingredients

BETNOVATE contains the active ingredient Betamethasone Valerate. Each 1 g contains 1.22 mg of betamethasone valerate (0.122% w/w).

The other ingredients are:

- methyl hydroxybenzoate
- xanthan gum
- cetostearyl alcohol
- liquid paraffin
- isopropyl alcohol
- glycerol
- cetomacrogol 1000
- sodium citrate
- citric acid monohydrate
- purified water

Supplier

Your BETNOVATE is supplied in New Zealand by:

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown Auckland
NEW ZEALAND

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