

# BETNOVATE®

*Betamethasone Valerate 0.122% w/w Lotion BP*

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## Consumer Medicine Information

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### 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 taking BETNOVATE against the risks this medicine could 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.

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### 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.

Your doctor may have prescribed BETNOVATE for another reason.

BETNOVATE is not addictive.

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### Before you use BETNOVATE

#### **Do not use if:**

You must not use BETNOVATE if:

- you have ever had an allergic reaction to Betamethasone Valerate, 'Beta™', 'Bivate™' or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- you have acne or 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))
- you have chickenpox
- you have cold sores or genital herpes (herpes simplex virus)
- you have itchy skin which is not inflamed
- the irritated area of skin is also infected.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering

**Do not use BETNOVATE to treat dermatitis or other skin irritations around your mouth, genitals or anus, unless specifically told to do so by your doctor.**

**Do not let BETNOVATE lotion get in your eyes.**

#### **Tell your doctor if:**

You must tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines.
- you are taking any other medicines, including medicines you buy without a prescription.
- you are breastfeeding, pregnant or trying to become pregnant.
- If you do use BETNOVATE when breastfeeding, don't use BETNOVATE on the breast area to ensure that the baby does not accidentally get BETNOVATE in their mouth
- you are taking other medicines including ritonavir and itraconazole. Some medicines may affect how BETNOVATE works or make it more likely that you'll have side effects.

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### How do I use BETNOVATE?

#### **How much to use**

Use BETNOVATE 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**

Apply a thin layer 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.

### ***How long to use it for***

BETNOVATE should not be used every day for more than four weeks at a time.

### ***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.

### ***Don't stop using BETNOVATE without advice***

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

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## **What do I do if I use too much? (Overdose)**

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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.

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

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## **While you are using BETNOVATE**

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### ***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.

### ***Things you must not do***

**Do not give this medicine to anyone else, even if their symptoms seem similar to yours.**

**Do not use BETNOVATE to treat any other complaints unless your doctor says to.**

### ***Things to be careful of***

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

**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.**

**Use only 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.**

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## **What are the side effects?**

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**Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking BETNOVATE, even if the problem is not listed below.**

Like other medicines, BETNOVATE can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- skin rash
- hot or burning sensation
- itching

**Tell your doctor immediately if you notice any of the following:**

- Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.
- Worsening of symptoms
- Skin pigmentation changes

**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.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

**Do not be alarmed by this list of possible side effects. You may not experience any of them.**

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## How do I store BETNOVATE?

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**Keep this medicine where children cannot reach it, such as in a locked cupboard.**

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

**Keep BETNOVATE out of direct sunlight.**

**Do not leave in a car, on window sill or in bathroom.**

**Keep BETNOVATE in its bottle until time to use it.**

**Return any unused or expired medicine to your pharmacist.**

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## Product description

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### *What BETNOVATE looks like*

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

### *Ingredients*

BETNOVATE contains the active ingredient Betamethasone Valerate. Each 1 g contains 1.22mg 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 and purified water.

### *Supplier*

Your BETNOVATE is supplied by:

GlaxoSmithKline NZ Limited  
AMP Centre  
Cnr Albert & Customs Streets  
Private Bag 106600  
Downtown Auckland  
NEW ZEALAND

## **Where to go for further information**

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

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