

BETNOVATE CREAM

Betamethasone valerate 0.1%

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What Betnovate is used for

Betnovate relieves the inflammatory and itching skin problems which are responsive to steroid including: eczema, psoriasis, dandruff, allergic reactions, insect bites, prickly heat and other conditions.

For children over the age of one year Betnovate is used for skin condition that has not responded to milder steroid creams or ointments.

How Betnovate works

Betnovate belongs to a group of medicines called steroids. Steroids help to reduce redness, swelling and irritation of the skin.

Before you use Betnovate

- When you must not use it

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
- face redness
- rashes around the mouth
- itchy skin which is not inflamed

- itchiness around the anus or genitals (penis and vagina)
- on children under 1 year

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

- Before you start to use it

If you are pregnant, or think you could be, or if you are planning to become pregnant, do not use Betnovate without talking to your doctor first.

If you are breast-feeding, you must check with your doctor before you use Betnovate.

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

- Taking other medicines

Some medicines may affect how Betnovate works or make it more likely that you will have side effects. Examples of these medicines include:

- Ritonavir (antiviral) and itraconazole (antifungal)

Tell your doctor or pharmacist if you are taking any of these. There are other medicines which may have a similar effect. It is therefore very important to tell your doctor or pharmacist if you are taking any other medicines, if you have taken any recently, or if you start taking a new one. This includes medicines bought without a prescription.

How to use Betnovate

- How much to use

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 intermittent dosing, to help stop your eczema from coming back.

For example, you may be advised to apply a thin film of Betnovate once daily, two times a week to areas of skin which have been affected by eczema, or to those areas where it is likely to re-appear.

In the more resistant lesions, such as the thickened plaques of psoriasis on elbows and knees, the effect of Betnovate can be enhanced, if necessary, by occluding the treatment area with polythene film.

- When to use it

Use Betnovate once or twice a day or exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How long to use it

Use up to 4 weeks until improvement occurs, then your doctor may reduce the frequency or your doctor may prescribe a weaker steroid for

you to use instead as your skin gets better.

If your condition does not improve after 2-4 weeks of treatment, speak to your doctor.

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

Therapy with Betnovate should be gradually discontinued.

- If you forget to use it

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 use too much (overdose)

If you apply a large amount of Betnovate or accidentally swallow a lot of Betnovate, it could make you ill. If you do swallow a large amount of Betnovate, rinse your mouth out with plenty of water and contact your doctor or pharmacist for advice.

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, and pharmacists treating you that you are taking Betnovate

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor. Do not give Betnovate to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Take special care with Betnovate

- Tell your doctor if you are allergic (hypersensitive) to betamethasone or any of the ingredients listed.
- If you experience blurred vision or other visual disturbances, do not drive or operate machines and speak to your doctor.
- 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 long term 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, including a child's nappy, make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.

Contact your doctor if an infection develops.

- Whilst using Betnovate 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.

Side Effects

Like all medicines Betnovate can have side effects although not everybody gets them. Side effects will affect your skin and may affect other parts of your body if a sufficient quantity of medicine is absorbed through the skin and enters your blood stream.

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 Betnovate and tell your doctor as soon as possible.

Common side effects

These may affect up to 1 in 10 people

- itchy skin
- local skin burning or pain

Very rare side effects

These may affect up to 1 in 10,000 people

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, or stretch marks
- skin wrinkling
- skin dryness
- the appearance of blood vessels under the surface of your skin
- skin pigmentation changes
- 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.

In children also look out for the following signs:

- delayed weight gain
- slow growth.

Very rare 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
- 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 (osteoporosis)

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Betnovate

- Storage

Keep out of the sight and reach of children.
Do not use Betnovate after the expiry date on the tube or carton (Exp).
Store below 30°C.

- Disposal

Do not dispose of medicines in wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help protect the environment.

Product Description

- What it looks like

Betnovate Cream is a smooth white cream. Betnovate Cream also contains chlorocresol 0.1% w/w as preservative.

- Ingredients

- Active ingredient(s)
Betamethasone valerate
(0.1% w/w)

- Inactive ingredient(s)
Chlorocresol, Cetomacrogol, Cetostearyl alcohol, White soft paraffin, Liquid paraffin, Sodium dihydrogen phosphate dihydrate, Phosphoric acid, Sodium hydroxide, Purified water.

For important information about some of the inactive ingredient(s) see “**While you are using it**”.

- MAL number
MAL19961263ARZ

Manufacturer

Glaxo Wellcome Operations
Barnard Castle,
U.K.

Product Registration Holder

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