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Package leaflet: Information for the user



# Betnovate Ointment

## betamethasone valerate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

- What Betnovate is and what it is used for
- What you need to know before you use Betnovate
- How to use Betnovate
- Possible side effects
- How to store Betnovate
- Contents of the pack and other information

### 1 What Betnovate is and what it is used for

Betnovate contains a medicine called betamethasone valerate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation. Betnovate is used to help reduce the redness and itchiness of certain skin problems, such as eczema, psoriasis and dermatitis.

### 2 What you need to know before you use Betnovate

#### Do not use Betnovate:

- if you are allergic (hypersensitive) to betamethasone valerate or any of the other ingredients of Betnovate (listed in section 6)
- on a child under 1 year
- to treat any of the following skin problems, it could make them worse:
  - scabs
  - severe flushing of skin on and around your nose (rosacea)
  - spotty red rash around your mouth (perioral dermatitis)
  - itching around your back passage or private parts
  - infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
  - itchy skin which is not inflamed

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Betnovate.

#### Warnings and precautions

Talk to your doctor or pharmacist before using Betnovate if:

- you have previously had an allergic reaction with another steroid
- you are applying Betnovate under an airtight dressing, including a child's nappy. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much.
- you have psoriasis, your doctor will want to see you more often.
- using for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- you are applying to a large surface area
- you are applying Betnovate on broken skin or within the skin folds.
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if Betnovate repeatedly enters the eye.
- you have an infection of the skin as this will need to be treated.
- you are applying to thin skin such as the face or on children as their skin is thinner than adults and as a result may absorb larger amounts. Dressing or bandages should not be used on children or on the face where Betnovate is applied. Use on children or on the face should be limited to 5 days.

Contact your doctor if you experience blurred vision or other visual disturbances.

If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment. 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.

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream/ointment without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

#### Other medicines and Betnovate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine, especially if you are taking ritonavir and itraconazole medications.

#### Pregnancy and breast-feeding and fertility

If you are pregnant or are breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### 3 How to use Betnovate

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### Using this medicine

- You usually apply Betnovate once or twice a day. This may be reduced as your skin begins to get better.
- Betnovate is for use on your skin only.
- Do not use more than the amount prescribed for you.

- Do not use on large areas of the body for a long time (such as every day for many weeks or months) - unless your doctor tells you.
- The germs that cause infections like warm, moist conditions under bandages or dressings so always clean the skin before a fresh dressing is put on.
- If you are applying Betnovate on someone else make sure you wash your hands after use or wear disposable plastic gloves.
- If your skin problem does not improve in 2 to 4 weeks, talk to your doctor.

#### Guidance on how to apply Betnovate

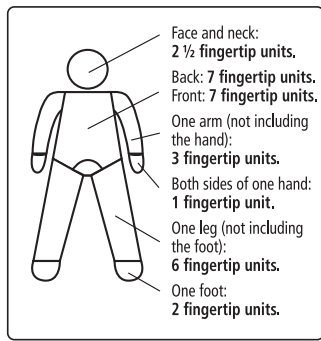
- Wash your hands.

- Apply a thin layer to the affected area(s) and gently rub into the skin until it has all disappeared. You can measure how much Betnovate to use with your fingertip. For children you will need to use less ointment but still use an adult finger to measure out the fingertip unit. This picture shows one fingertip unit.



- Unless you are meant to apply Betnovate to your hands as a part of the treatment, wash them again after using Betnovate.

#### For an adult



Do not worry if you find you need a little more or less than this. It is only a rough guide.

#### For a child aged 1 – 10

Child's age	Number of fingertip units needed				
	Face and neck	Arm and hand	Leg and foot	Front	Back including buttocks
1-2 years	1 ½	1 ½	2	2	3
3-5 years	1 ½	2	3	3	3 ½
6-10 years	2	2 ½	4 ½	3 ½	5

- Do not use it on children under 1 year of age.
- It is especially important in children not to exceed the prescribed amount.
- A course of treatment for a child should not normally last more than 5 days - unless your doctor has told you to use it for longer.

#### If you have psoriasis

If you have thick patches of psoriasis on your elbows or knees, your doctor may suggest applying Betnovate under an airtight dressing. It will only be at night to help Betnovate to start working. After a short period of time you will then apply Betnovate as normal.

#### If you apply Betnovate to your face

You should only apply Betnovate to your face if your doctor tells you to. It should not be used for more than 5 days, as the skin on your face thins easily. **Do not let Betnovate get into your eyes.**

#### If you use more Betnovate than you should

If you apply too much or if accidentally swallowed, it could make you ill. Talk to your doctor or go to the hospital as soon as possible.

#### If you forget to use Betnovate

If you forget to apply Betnovate, apply it as soon as you remember. If it is close to the time you are next meant to apply it, wait until this time.

#### If you stop using Betnovate

If you use Betnovate regularly make sure you talk to your doctor before you stop using it as your condition may get worse if stopped suddenly.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### Stop using Betnovate and tell your doctor immediately if:

- you find that your skin condition gets worse, you develop a generalised rash or your skin becomes swollen during treatment. You may be allergic to Betnovate, have an infection or need other treatment.
- you have psoriasis and get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.

#### Other side effects you may notice when using Betnovate include:

**Common:** may affect up to 1 in 10 people

- a feeling of burning, pain, irritation or itching where Betnovate is applied.

**Very rare:** may affect up to 1 in 10,000 people

- an increased risk of infection
- an allergic skin reaction where Betnovate is applied
- rash, itchy bumpy skin or redness of the skin
- thinning and dryness of your skin and it may also damage or wrinkle more easily
- stretch marks may develop
- blood vessels under the surface of your skin may become more noticeable
- an increase or reduction in hair growth or hair loss and changes in skin colour
- weight gain, rounding of the face
- delayed weight gain or slowing of growth in children
- bones can become thin, weak and break easily
- cloudy lens in the eye (cataract) or increased pressure in eye (glaucoma)
- a decrease in the level of the hormone cortisol in your blood
- increased blood sugar levels or sugar in the urine
- high blood pressure

**Not known:** frequency cannot be estimated from the available data

- blurred vision
- Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

To report Product Complaints or Adverse Event/s associated with the use of GSK product/s, please contact us via: [gulf.safety@gsk.com](mailto:gulf.safety@gsk.com)

By reporting side effects you can help provide more information on the safety of this medicine.

### 5 How to store Betnovate

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the tube or carton after (EXP). The expiry date refers to the last day of that month.
- Do not store above 30°C
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6 Contents of the pack and other information

#### What Betnovate ointment contains

- The active ingredient is betamethasone valerate. Each 1 g contains 1 mg of betamethasone (0.1% w/w) as valerate.

The other ingredients are Liquid Paraffin Ph. Eur. and White Soft Paraffin Ph. Eur

#### What Betnovate looks like and contents of the pack

Within each carton is a tube with a plastic screw cap, which contains 30 g of ointment.

#### Marketing Authorisation Holder

Glaxo Wellcome UK Limited, GSK Medicines Research Centre, Gunnels Wood Road, Stevenage, Hertfordshire, SG1 2NY, United Kingdom

#### Manufacturer

Glaxo Operations UK Limited  
Barnard Castle, UK

If you have any questions or are not sure about anything, ask your doctor or pharmacist who will advise you.

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THIS IS A MEDICAMENT
Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.
Council of Arab Health Ministers, Union of Arab Pharmacists.

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<b>Material Type:</b> N/A	N/A	
<b>Total Colours &amp; Varnishes: 1</b>		
BLACK		
<b>Total Special Finishes: 0</b>		
<b>Body Text Size:</b> 6.0pt		
<b>Smallest Text Size:</b> 6.0pt		
<b>Leading:</b> 6.5pt		
<b>Horizontal Scale:</b> 100%		
<b>Microtext:</b> N		
<b>Additional Info (1):</b> N/A		
<b>Additional Info (2):</b> N/A		
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200 mm Measuring Bar

## IMPORTANT

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**Artwork Studio is responsible for site technical requirements and pre-press suitability.**

**GSK Market is responsible to advise SDC when changes required impact the following:**

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