

# BETNOVATE-N CREAM

Betamethasone 17-valerate/neomycin sulphate (0.1/0.5% w/w)

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## What BETNOVATE-N is used for

BETNOVATE-N relieves the symptoms of certain skin problems which may be infected, including: eczema, psoriasis, lichen simplex, lichen planus, contact sensitivity reactions, insect bites and other conditions.

## How BETNOVATE-N works

The name of your medicine is BETNOVATE-N. BETNOVATE-N contains betamethasone valerate which belongs to a group of medicines called steroids and neomycin sulphate which is an antibiotic. Steroids help to reduce redness, swelling and irritation of the skin. Antibiotics help to treat bacterial infections.

## Before you use BETNOVATE-N

- When you must not use it

Do not use BETNOVATE-N

- on children under 2 years
- on large areas for a prolonged period of time

- to treat any of the following skin problems - it could make them worse:
  - viral infections such as cold sores, herpes or chicken pox
  - fungal infections such as ringworm, athlete's foot, or thrush
  - acne
  - face redness
  - rashes around the mouth
  - itchy skin which is not inflamed
  - inflamed, red, flaky skin of the outer ear and ear canal if your ear drum is perforated
  - itching around the anus or genitals (penis and vagina).

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

- Before you start to use it

- Tell your doctor if you are allergic (hypersensitive) to BETNOVATE-N or any of the ingredients of BETNOVATE-N.
- Do not dilute BETNOVATE-N.
- If you experience blurred vision or other visual disturbances, speak to your doctor.
- If you have eczema around a leg ulcer, using 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-N 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.

- Whilst using BETNOVATE-N 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 are pregnant, or think you could be, or if you are planning to become pregnant, do not use BETNOVATE-N without talking to your doctor first.

If you are breast-feeding, do not use BETNOVATE-N without talking to your doctor first.

- Taking other medicines

Some medicines may affect how BETNOVATE-N works or make it more likely that you'll have side effects. Examples of these medicines include:

- Ritonavir and itraconazole
- Neuromuscular blocking agents such as gallamine, mivacurium, pancuronium
- Other medicines that contain neomycin

Tell your doctor or pharmacist if you are taking any of these.

There are other medicines which may have a similar effect. It's 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-N

- How much to use

Always use BETNOVATE-N exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Use BETNOVATE-N once or twice a day. Your doctor will tell you how often to use this medicine. The number of times you use your medicine may be reduced as your skin gets better. Your doctor may also prescribe another steroid that does not contain neomycin 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-N to be absorbed after each application before applying the emollient.
- This medicine should not be used every day for more than 7 days without talking to your doctor first.

- When to use it

Check with your doctor or pharmacist.

- How long to use it

Only use BETNOVATE-N for as long as your doctor recommends. If your condition does not improve after 7 days of treatment, speak to your doctor.

- If you forget to use it

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

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

- If you use too much (overdose)

If you apply a large amount of BETNOVATE-N or accidentally swallow a lot of BETNOVATE-N, it could make you ill. If you do swallow a large amount of BETNOVATE-N, 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

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

- Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- Things to be careful of

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

Take care when applying BETNOVATE-N to the face over a long period of time as it may cause skin thinning. Contact your doctor if an infection develops. Antibiotics may cause a condition that can result in severe diarrhoea and stomach cramps. Although this is unlikely to happen with antibiotics applied to the skin, if you develop stomach cramps or diarrhoea that does not improve or is severe, stop using BETNOVATE-N and contact your doctor immediately.

**Side Effects**

Like all medicines BETNOVATE-N 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-N 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-N 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
- changes to the colour 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.

The following very rare side effects may also occur in children:

- 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 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 any of the side effects listed become 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](http://npra.gov.my) (Consumers → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI))

### Storage and Disposal of BETNOVATE-N

#### - Storage

- Keep out of the reach and sight of children. It may harm them.
- Do not use BETNOVATE-N after the expiry date on the tube or carton (Exp).
- Store below 30°C

#### - Disposal

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

### Product Description

#### - What it looks like

BETNOVATE-N Cream is a smooth white to off-white cream.

BETNOVATE-N cream is packed in a collapsible aluminium tube, internally coated with an epoxy resin based lacquer and closed with a wadless polypropylene cap.

#### - Ingredients

- Active ingredient(s)

Betamethasone 17-valerate,  
Neomycin sulphate

- Inactive ingredient(s)

Chlorocresol, Sodium dihydrogen phosphate dihydrate, Cetomacrogol 1000, Cetostearyl alcohol, Liquid paraffin, White soft paraffin, Phosphoric acid, Sodium hydroxide, Purified water.

For important information about some of the inactive ingredient(s) see “**Before you use BETNOVATE-N**”.

#### - MAL number

MAL19961681ACRZ

### Manufacturer

Delpharm Poznań Spółka Akcyjna  
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60-322 Poznań  
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### Product Registration Holder

GlaxoSmithKline  
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