

Package leaflet: Information for the patient

Betamethasone valerate/Neomycin sulfate 1 mg/5 mg/g Cream

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:

1. What Betamethasone/Neomycin Cream is and what it is used for
2. What you need to know before you use Betamethasone/Neomycin Cream
3. How to use Betamethasone/Neomycin Cream
4. Possible side effects
5. How to store Betamethasone/Neomycin Cream
6. Contents of the pack and other information

1. What Betamethasone/Neomycin Cream is and what it is used for

Betamethasone/Neomycin Cream contains two different medicines called betamethasone valerate and neomycin sulfate.

- Betamethasone valerate belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.
- Neomycin sulfate is a type of anti-infective medicine. It fights bacterial infections of the skin.

This medicine is used to help reduce the redness and itchiness of certain skin problems. These skin problems include eczema, psoriasis, dermatitis or insect bites, where an infection may be a problem.

2. What you need to know before you use Betamethasone/Neomycin Cream

Do not use Betamethasone/Neomycin Cream:

- if you are allergic to betamethasone valerate, neomycin sulfate or any of the other ingredients (listed in section 6)
- on a child under 2 years old
- to treat any of the following skin problems, it could make them worse:
 - acne
 - 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 - unless your doctor has told you to do so
 - viral infections, such as cold sores, herpes or chicken pox
 - fungal infections, such as ringworm, athlete's foot or thrush
 - skin blisters or sores that are caused by an infection
 - outer ear infections.

If any of the above apply to you, speak to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using Betamethasone/Neomycin Cream if

- you are applying the cream 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 cream
- you have psoriasis, your doctor will want to see you more often
- you have kidney problems; your doctor may decide to change the amount or number of times you apply the cream.

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. If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your prescriber unless your prescriber has previously advised you to 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.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings 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 not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Other medicines and Betamethasone/Neomycin Cream

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal products.

If Betamethasone/Neomycin Cream is absorbed into the body in large amounts, the effects of medicines used to relax muscles during surgery can last longer or even be increased. If you are having surgery you should tell the doctor that you have used Betamethasone/Neomycin Cream.

Pregnancy and breast-feeding

If you are pregnant or 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.

Driving and using machines

Betamethasone/Neomycin Cream is unlikely to affect your ability to operate machinery or to drive.

Betamethasone/Neomycin Cream contains chlorocresol and cetostearyl alcohol including cetyl alcohol

This medicine contains chlorocresol, which may cause allergic reactions. This medicine also contains cetostearyl alcohol including cetyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

3. How to use Betamethasone/Neomycin Cream

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 the cream 2 or 3 times a day. This may be reduced as your skin begins to get better.

- **If your skin problem does not improve after 7 days talk to your doctor.**
- This cream is for use on your skin only.
- 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 to.
- The germs that cause infections like warm and moist conditions under dressings so always clean the skin before a fresh dressing is put on.
- If you are applying the cream on someone else make sure you wash your hands after use or wear disposable plastic gloves.
- Do not mix with any other creams or ointments.

Guidance on how to apply the cream

1. Wash your hands.
2. Gently rub the correct amount of cream into the skin until it has all disappeared. You can measure how much cream to use with your fingertip. This picture shows one fingertip unit.
3. Unless you are meant to apply the cream to your hands as a part of the treatment, wash them again after using the cream.

For an adult

You should find that:

- two fingertips of cream will cover both hands or one foot
- three fingertips of cream will cover one arm
- six fingertips of cream will cover one leg
- fourteen fingertips of cream will cover the front and back of the body.
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Do not worry if you find you need a little more or a little less than this. It is only a rough guide.

For a child

- Do not use it on children under 2 years of age.
- The smaller the child the less you will need to use.
- A child of 4 years needs about a third of the adult 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 the cream under an airtight dressing. It will only be at night to help the cream to start working. After a short period of time you will then apply the cream as normal.

If you apply Betamethasone/Neomycin Cream to your face

You should only apply the cream to your face if your doctor tells you to. The cream should not be used for too long as the skin on your face thins easily. **Do not let the cream get into your eyes.** If it does, wash it out with plenty of water.

If you use more Betamethasone/Neomycin Cream than you should

If, by mistake on a few occasions you use more than you should, do not worry. If you apply a lot or if a lot is accidentally swallowed, it could make you ill. Talk to your doctor or go to your hospital as soon as possible.

If you forget to use Betamethasone/Neomycin Cream

If you forget to use the cream, use it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual.

Do not use a double dose to make up for a forgotten dose.

If you stop using Betamethasone/Neomycin Cream

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

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

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency.

Betamethasone/Neomycin Cream is classed as a strong corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

4. Possible side effects

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

STOP using this medicine and tell your doctor as soon as possible if:

- you find that your skin problem gets worse or becomes swollen during treatment. You may be allergic to the cream or need other treatment.

Other side effects you may notice when using Betamethasone/Neomycin Cream include:

- a feeling of burning, irritation or itching where the cream is applied
- if you have psoriasis you may get raised bumps with pus under the skin. This can happen during or after the treatment and is known as pustular psoriasis.

Side effects if you use Betamethasone/Neomycin Cream for a long time, or you use a lot each time you apply it, or you apply it under an airtight dressing or a nappy:

- stretch marks may develop
- veins under the surface of your skin may become more noticeable
- increased hair growth and changes in skin colour
- thinning of your skin that may also damage more easily
- weight gain, rounding of the face and high blood pressure. These are more likely to happen in infants and children.

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.

If you absorb or swallow Betamethasone/Neomycin Cream in large quantities, it can affect your hearing, nerves and kidneys. This is unlikely when you use the cream normally.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Betamethasone/Neomycin Cream

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tube end or carton after Exp. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any 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 Betamethasone/Neomycin Cream contains

- The active substances are betamethasone valerate and neomycin sulfate. Each 1 g contains 1 mg of betamethasone (0.1% w/w) as valerate and 5 mg of neomycin sulfate (0.5% w/w).
- The other ingredients are: chlorocresol, cetomacrogol 1000, cetostearyl alcohol, white soft paraffin, liquid paraffin, sodium acid phosphate, phosphoric acid, sodium hydroxide and purified water. (See end of section 2 for further information on chlorocresol and cetostearyl alcohol including cetyl alcohol).

What Betamethasone/Neomycin Cream looks like and contents of the pack

Within each carton is a tube with a plastic screw cap, which contains 15 g, 30 g or 100 g of cream. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Essential Generics, 8a Crabtree Road, Egham, Surrey TW20 8RN, United Kingdom.

Manufacturer

Purna Pharmaceuticals NV, Rijksweg 17, 2870 Puurs, Belgium.

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