

Package leaflet: Information for the patient

Betasonone-N Cream

Betamethasone valerate and Neomycin sulfate

Read all of this leaflet carefully before you start taking 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 Betasonone-N is and what it is used for
2. What you need to know before you use Betasonone-N
3. How to use Betasonone-N
4. Possible side effects
5. How to store Betasonone-N
6. Contents of the pack and other information

1. What Betasonone-N is and what it is used for

The name of your medicine is Betasonone -N. Betasonone -N contains betamethasone valerate which belongs to a group of medicines called steroids and neomycin sulfate which is an antibiotic.

Steroids help to reduce redness, swelling and irritation of the skin. Antibiotics help to treat bacterial infections.

Betasonone -N cream relieves the symptoms of certain skin problems which may be infected:

- Eczema
- Prurigo nodularis (itchy nodules on the arms or legs)
- Psoriasis (thickened patches of inflamed, red skin, often covered by silvery scales)
- Lichen simplex chronicus (patches of thickened, itchy skin, caused by scratching)
- lichen planus (a skin disease that causes itchy, reddish-purple, flat-topped bumps on the wrists, forearms or lower legs)
- Seborrheic dermatitis (a red, scaly, itchy rash that develops on the face, scalp, chest and back)

- Skin rash due to allergy or a substance that irritates your skin (irritant and allergic contact dermatitis)• Anal or genital intertrigo (skin irritation in the

anal or genital area where skin rubs against skin, clothing, or other material)

- Otitis externa (inflamed, red, flaky skin of the outer ear and ear canal)
- Insect bites
- Prickly heat

2. What you need to know before you use Betasonone-N Cream

Do not use Betasonone-N Cream:

- 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:

o viral infections such as cold sores, herpes or chicken pox

o fungal infections such as ringworm, athlete's foot, or thrush

o acne

o 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))

o rashes around the mouth

o itchy skin which is not inflamed

o inflamed, red, flaky skin of the outer ear and ear canal if your ear drum is perforated

o itching around the anus or genitals (penis and vagina).

If you think any of these apply to you, don't use Betasonone -N Cream until you have checked with your doctor or pharmacist.

Warnings and precautions

- Tell your doctor if you are allergic (hypersensitive) to Betasonone -N Cream or any of the ingredients (listed in Section 6).
- Don't dilute Betasonone -N Cream.
- Only use Betasonone -N Cream for as long as your doctor recommends. If your condition does not improve after 7 days of treatment, speak to your doctor.
- Take care when applying Betasonone -N Cream to the eyelids to make sure it does not get into your eye.

- Take care when applying Betasonone -N Cream to the face over a long period of time as it may cause skin thinning.

• 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 Betasonone -N Cream 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 (See Section 4 Possible Side Effects).

Other medicines and Betasonone -N

Some medicines may affect how Betasonone -N Cream 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're taking any other medicines, if you've taken any recently, or if you start taking a new one. This includes medicines bought without a prescription.

Pregnancy and breast-feeding

If you are pregnant, or think you could be, or if you are planning to become pregnant, don't use Betasonone -N Cream without talking to your doctor first.

If you are breast-feeding, don't use Betasonone -N Cream without talking to your doctor first.

Betasonone-N contains Cetyl alcohol

Cetyl alcohol may cause local skin reactions.

Betasonone-N contains Propylene glycol.

Propylene glycol may cause skin irritation. Do not use this medicine in babies less than 4 weeks old with open wounds or large areas of broken or damaged skin (such as burns) without talking to your doctor or pharmacist.

Betasonone-N contains Methyl paraben and Propyl paraben.

Methyl paraben and Propyl paraben may cause allergic reactions (possibly delayed).

Betasonone-N contains Ethanol

Ethanol may cause burning sensation on damaged skin.

3. How to use Betasonone-N Cream

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

How much to use

• Use Betasonone -N Cream 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 doesn't 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 (moisturizing) preparation allow time for Betasonone -N Cream 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.

If you forget to use Betasonone -N Cream

- If you forget to use Betasonone -N CREAM apply it as soon as you remember then continue as before.
- Do not apply extra Betasonone-N CREAM to make up for missed doses.

If you use too much Betasonone -N Cream

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

Like all medicines Betasonone -N Cream 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.

4. Possible side effects

Common side effects (may affect up to 1 in 10 people)

- Itchy skin
- Local skin burning or pain

Very rare side effects (may affect up to 1 in 10,000 people)

Use of Betasonone -N Cream 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 color 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.

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

5. How to store Betasonone-N

- 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 and the outer box. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. 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 Betasonone-N contains

The active ingredients are Betamethasone valerate and Neomycin. Each 1 g contains 1.21 mg of Betamethasone valerate, equivalent to 1 mg of Betamethasone (0.1%), and 5 mg of Neomycin sulfate, equivalent to 3.5 mg Neomycin (0.35%). The other ingredients are Polysorbate 60, Cetyl Alcohol, Paraffin, Stearyl alcohol, Propylene glycol, Methyl paraben, Propyl paraben, Ethanol and Water.

What Betasonone-N looks like and contents of the pack

Betasonone-N comes in a tube containing 15 g of white cream, packed in a carton.

Marketing Authorization Holder and Manufacturer

Pharmaline s.a.l. – Lebanon
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Website: www.pharmaline.com.lb
Betasonone-N Reg. N° Lebanon 26589/89

This is a medicament

- A 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 experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- 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

The leaflet was last revised in April 2022.