

PACKAGE LEAFLET: Information for the patient

DEXA-NEO

Cream – (0.15% / 0.5%)

(Dexamethasone sodium phosphate, Neomycin sulphate)

Read all of this leaflet carefully before you start using this medicine.

- 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.

What is in this leaflet:

1. What Dexa-Neo is and what it is used for
2. What you need to know before you use Dexa-Neo
3. How to use Dexa-Neo
4. Possible side effects
5. How to store Dexa-Neo
6. Other information

1. WHAT DEXA-NEO IS AND WHAT IT IS USED FOR

Dexa-Neo is a pharmaceutical product that contains the active substances dexamethasone sodium phosphate and neomycin sulphate. Dexamethasone sodium phosphate is a synthetic glucocorticoid, analogue of natural glucocorticoids, with strong anti-inflammatory and anti-allergic activity. Neomycin sulphate is a broad-spectrum antibiotic, with a bactericidal activity against Gram-negative and Gram-positive microorganisms.

Dexa-Neo is used:

- as a short-term treatment in inflammatory skin diseases that respond to steroids, where is also required a prophylactic treatment with antibiotics, only after the exclusion of the viral and fungal diseases; it has also a local action as anti-pruritic and vasoconstrictor although the mechanism of action of the corticosteroids is not yet very clear;
- for the treatment of skin diseases, when there is a secondary infection like eczema, psoriasis, dermatitis, neurodermatitis, contact sensitivity reactions;
- for the treatment of secondary infections by insect bites as well as for the treatment of anogenital pruritus.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DEXA-NEO

Do not use Dexa-Neo:

- if you are sensitive (allergic) to glucocorticoids, aminoglycosides or to any of the excipients of Dexa-Neo cream, as allergic reactions can occur, including anaphylaxis; aminoglycosides allergic reactions are not common, but when they occur, often are cross-sensitivity reactions.

Dexa-Neo contains dexamethasone sodium phosphate. For this reason, it should not be used:

- on areas of the skin with viral (herpes simplex, chickenpox), fungal or bacterial infections;
- in the face, in cases of rosacea, perioral dermatitis and also in wounds and fresh ulcerations.

Take special care with Dexa-Neo

In severe infections, local treatment must be combined with an appropriate systemic treatment. Treatment with Dexa-Neo should not continue for a long period, because it can cause atrophic changes of the skin. Also, the steroid can inhibit the adrenal glands, and neomycin sulphate can cause hypersensitivity reactions and development of resistant microorganisms. Corticosteroids used locally can mask or activate skin infections; in such cases it is necessary an antibiotic therapy.

Dexa-Neo cream has a corticosteroid composition (dexamethasone sodium phosphate) and this is why it should be used with caution in:

- patients with peripheral vascular disease because of the risk of skin ulcerations,

- children, because during the local use of the corticosteroid, they absorb larger quantities of the drug, thus being more prone to the occurrence of systemic side effects.

It must be taken into account the possibility of the systemic action of corticosteroids in case of a long - time usage and in large areas, especially under occlusive dressings.

Talk to your doctor if you experience swelling and weight gain around the trunk and in the face as these are usually the first manifestations of a syndrome called Cushing's syndrome.

Suppression of the adrenal gland function may develop after stopping a long-term or intensive treatment with Dexa-Neo. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a drug called ritonavir.

Other medicines and Dexa-Neo

Tell your doctor or pharmacist if you are taking / using or you have taken / used any other medicines, including those obtained without a prescription. Do not forget to inform your doctor about Dexa-Neo cream, if you get another drug during treatment.

Since Dexa-Neo contains neomycin sulphate, if combined with other ototoxic or nephrotoxic drugs, the increased possibility of the occurrence of side effects with a toxic nature should be considered. Absorption after local use of neomycin sulphate may be sufficient to produce interactions with other drugs given systemically.

Tell your doctor if you are using ritonavir, as this may increase the amount of dexamethasone in the blood.

Pregnancy and breastfeeding

Talk to your doctor or pharmacist before using Dexa-Neo.

Dexa-Neo should not be used during pregnancy and lactation since there is no accurate information about its safety. It can only be used in such cases if the benefits for the mother justify the risks that appear to the fetus or baby and always under the advice of a specialist.

Driving and using machines

This medicinal product does not present any influence on the ability to drive and use machines.

Important information about some of the excipients of Dexa-Neo

This product contains methylhydroxybenzoate and propylhydroxybenzoate, which may cause allergic reactions (possibly delayed).

This product contains propylene glycol, which can cause skin irritation.

3. HOW TO USE DEXA-NEO

Your doctor will inform you for the quantity of Dexa-Neo to be used and when to use it. It is important to exactly follow the instructions of your doctor and never change the dose by yourself, no matter how you feel.

Ask your doctor or pharmacist if you are not sure.

Dexa-Neo should be applied no more frequently than twice daily. The cream should be spread thinly on the skin but in sufficient quantity to cover the affected areas. Once inflammation is controlled, the frequency of application should be reduced. Treatment should last only a few weeks (1 – 3 weeks).

If you use more Dexa-Neo than you should

If you use more Dexa-Neo, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for actions to be taken.

Side effects from the overdose of Dexa-Neo rarely occur. The possibility of a systemic action exists if used for a long time and in a large area, especially under occlusive dressings.

If you forget to use Dexa-Neo

If you forget a dose of Dexa-Neo, use the following dose as soon as you can, except the case when it is almost time to use the next dose.

Do not use a double dose of Dexa-Neo to make up for the forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Dexa-Neo can cause side effects, although not everybody manifests them. Most of the side effects are dose-related and disappear when the dose is reduced or when the treatment is interrupted. Some of the side effects can occur at the beginning of the treatment and disappear spontaneously with continuation of the treatment.

When the cream is used in continuous or repeated form, there is the risk of occurrence of sensitization reactions and of the systemic action.

During local use (on the skin) of corticosteroids, although rarely, irritation, burning or itching sensation, xerosis (dry skin), hypopigmentation, folliculitis, acneiform rash, perioral dermatitis, miliaria, rosacea, allergic contact dermatitis, secondary infections, skin atrophy, telangiectasias, sensitivity to light may occur. Hormone problems with unknown frequency (frequency cannot be estimated from the available data) may also develop, such as: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the levels of protein and calcium in your body, stunted growth in children and teenagers and swelling and weight gain of the body and face (called Cushing's syndrome) (see section 2, "Take special care with Dexa-Neo").

During local use with neomycin sulphate hypersensitivity reactions may occur (usually delayed-type), causing irritation, burning, itching, dermatitis, and edema. The ototoxic effect of neomycin sulphate is more powerful than that of other aminoglycosides. When used in large areas and for a long time, in open wounds and damaged skin, it can cause tinnitus, vertigo and partial or complete deafness, which is irreversible. This effect is dose - related and strengthened in the case of kidney and liver function damage.

If any of the side effects worsens, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DEXA-NEO

Keep in the original package, in a dry and cool place, at a temperature not higher than 25°C.

Do not use this medicine after the expiry date which appears on the package.

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

6. OTHER INFORMATION

What Dexa-Neo contains:

The **active substances** are dexamethasone sodium phosphate and neomycin sulphate.

1 g cream contains 1.5 mg (0.15%) of dexamethasone sodium phosphate and 5 mg (0.5%) of neomycin sulphate.

The **excipients** are: white soft paraffin, light liquid paraffin, propylene glycol, methylhydroxybenzoate, propylhydroxybenzoate, PEG-6 stearate glycol stearate PEG-32 stearate, purified water.

Content of the pack

Box with a tube of 15 g.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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