

PACKAGE LEAFLET: Information for the patient

DEXA-NEO

Eye ointment – (0.5 mg + 5 mg) / g

Eye drops solution – (0.1% + 0.5%)

(Dexamethasone sodium phosphate, Neomycin sulfate)

Read 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Dexa-Neo is and what it is used for
2. Before you use Dexa-Neo
3. How to use Dexa-Neo
4. Possible side effects
5. How to store Dexa-Neo
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1. WHAT DEXA-NEO IS AND WHAT IT IS USED FOR

Dexa-Neo contains the active substances dexamethasone sodium phosphate and neomycin sulfate. Dexamethasone sodium phosphate is a synthetic glucocorticoid, analogous of the natural glucocorticoids, with powerful anti-inflammatory and anti-allergic properties. Neomycin is a broad-spectrum antibiotic with a bactericidal action against gram-negative and gram-positive microorganisms. Neomycin sulphate is an aminoglycoside antibiotic, active against most common pathogenic agents that are present in the eye such as *Staphylococcus aureus*,

Escherichia coli, *Haemophilus influenzae*, *Klebsiella/Enterobacter* species, and *Neisseria* species.

Dexa-Neo is used:

- for steroid-responsive inflammatory ocular conditions for which a steroid antiinflammatot is indicated and where bacterial infection or a risk of bacterial ocular infection exists;
- in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe where the inherent risk of steroid use is accepted to obtain a diminution in edema and inflammation;
- in chronic anterior uveitis and corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies;
- in conditions where the risk of infection is high.

2. BEFORE YOU USE DEXA-NEO

Do not use Dexa-Neo if you:

- are sensitive (allergic) to glucocorticoids, where dexamethasone sodium phosphate is part and aminoglycosides, where neomycin is part or to any of the excipients of the medicinal product since allergic reactions can occur, including anaphylaxis; allergic reactions from aminoglycosides are not common, but when they occur, are often crossed within the chemical group;
- have other viral diseases of the cornea and conjunctiva, including *herpes simplex*;
- have an eye fungal infection;
- have ocular tuberculosis;
- have purulent untreated ocular infections.

Take special care with Dexa-Neo

- Prolonged use of corticosteroids may result in ocular hypertension / glaucoma with damage of the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation.
- Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera,

perforations have been known to occur with the use of topical corticosteroids. In acute purulent conditions of the eye, corticosteroids may mask or exacerbate the existing infection.

- If Dexa-Neo is used for 10 days or longer, intraocular pressure should be routinely monitored.
- Dexa-Neo should be used with caution in patients with ocular hypertension and/or glaucoma. In this case intraocular pressure should be checked more frequently.
- The use of corticosteroids after cataract surgery may delay healing and increase the incidence of filtering blebs.
- Use of ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including *herpes simplex*). The use of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution and periodic ophthalmological examination.
- Corticosteroids for local use, should never be used for an undiagnosed red eye infection because their inappropriate use may constitute a danger for loss of vision.
- Prolonged treatment with neomycin sulfate should be avoided because it may cause hypersensitivity reactions in the skin and the appearance of resistant microorganisms. In severe infections, local treatment should be completed with an appropriate systemic treatment.
- The use of ophthalmic corticosteroids in patients wearing contact lenses can enhance the possibility of eye infections.
- Talk to your doctor if you experience swelling and weight gain around the trunk and in the face. 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. These risks are especially important in children and patients treated with a drug called ritonavir or cobicistat.

Talk to your doctor if you have blurred vision or other vision problems.

Taking other medicines

Please contact your doctor or pharmacist if you are taking / using, have recently taken / used other medicines, including medicines obtained without a prescription.

It is especially important that your doctor be aware of the fact that you are treated with:

- antimuscarinic drugs because concomitant use of antimuscarinic drugs with ophthalmic corticosteroids increases the probability of occurrence of glaucoma;
- other drugs that treat glaucoma since corticosteroids increase intraocular pressure so they can reduce the effectiveness of these drugs;
- ritonavir or cobicistat because they may increase dexamethasone blood concentration.

Neomycin increases the risk of nephrotoxicity when it is given with cyclosporin, cytotoxics and other antibacterials, and the risk of ototoxicity when it is given with other antibacterials (capreomycin and vancomycin), cytotoxics and loop diuretics etc.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using this medicine.

The use of Dexa-Neo should be avoided during pregnancy (Category C).

Dexa-Neo should be used during pregnancy and breastfeeding only if the potential benefit outweighs the potential risk to the fetus or infant and always with a doctor's recommendation.

Driving and using machines

Like all ophthalmic preparations, Dexa-Neo may cause temporarily blurred vision or other visual disturbances that may affect the ability to drive or use machines. If blurred vision occurs, the patient must wait until the vision clears before driving or using machines.

Important information about some of the excipients of Dexa-Neo

Dexa-Neo, eye drops solution, contains 0.5 mg benzalkonium chloride in a flacon of 5 ml which may cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Benzalkonium chloride is known to discolour soft contact lenses.

Dexa-Neo, eye ointment contains methyl hydroxybenzoate (nipagin), which may cause allergic

reactions (possibly delayed).

3. HOW TO USE DEXA-NEO

Your doctor will inform you for the quantity of Dexa-Neo that should be used and when it should be used. It is important to follow your doctor's instructions strictly and never change the dose, no matter how you feel.

Ask your doctor or pharmacist if you are not sure about the dose that you should use and when to use it.

Duration of treatment depends on the damage and may vary from a few days to several weeks, based on therapeutic response.

Apply Dexa-Neo, eye drops solution, 1 – 2 drops into the conjunctival sac every 1 hour during the day and every 2 hours during the night as initial therapy. When a favorable response is observed, reduce dosage to 1 drop every 4 hours. Later, further reduction in dosage to 1 drop 3 – 4 times daily, until the symptoms improve.

Apply Dexa-Neo, eye ointment, 3 – 4 times a day as initial therapy. When a favorable response is observed, reduce dosage to twice a day and later further reduction in dosage to once a day to control symptoms.

No more than 3 tubes of eye ointment or 4 vials of eye drops solution should be given without performing a complete examination of the patient by the specialist.

The initial prescription and renewal of the medication should be made by a doctor only after examination of the patient with a biomicroscope etc. If the treatment lasts more than 10 days, intraocular pressure should be monitored.

The method of administration is:

- Wash your hands thoroughly.
- The tip of the container should not come in contact with the eyelashes, conjunctiva, skin, fingers or other surfaces.
- Don't use the same tube / bottle in more than one patient because of the risk to spread

infection.

- Look up.
- Pull down your lower eyelid to form a pouch.
- Put the tip of the container close to your lower eyelid without touching it.
- Release the required number of drops or the required quantity of ointment into the pouch.
- Close your eye for about 2 minutes.
- Excess solution / ointment that emerges can be removed with a sterile gauze.
- The medicine should be kept closed when it is not used, because if used without caution, it can be contaminated and may cause eye infections which lead in serious eye damages and visual impairment.
- If during treatment, redness, irritation, oedema or pain in the eye continue or aggravate, treatment should be discontinued and the patient should consult a specialist. Also, in cases when the patient has undergone eye surgery or suffered a trauma, he should also consult the ophthalmologist immediately.
- The drug should be kept in places that can not be reached by children.
- The drug may be used during pregnancy, breast-feeding and in children only if the potential benefit outweighs the potential risk, and it should be for a short time.

If you use more Dexa-Neo than you should

If you use more Dexa-Neo than you should, or if the children have accidentally taken this drug, please contact your doctor, hospital or emergency to get an opinion on the risk and advice on the actions that should be taken.

Side effects from overdose with Dexa-Neo occur rarely.

If you forget to use Dexa-Neo

If you forget to use a dose of Dexa-Neo, use it as soon as you remember. If it is almost time for the next dose, use it and pass the forgotten dose. Do not use an extra dose of Dexa-Neo to make up a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dexa-Neo can cause side effects, although not everybody gets them.

Most of the side effects are dose-related and disappear when the dosage is reduced or treatment is stopped. Some side effects may occur at the beginning of treatment and spontaneously disappear when the treatment continues.

The most common side effects of Dexa-Neo:

- It may result in increased intraocular pressure, the severity of which depends on the dose and duration of treatment. This effect, normally, disappears upon cessation of treatment.
- Ophthalmic use of Dexa-Neo delays healing of corneal ulcers and rarely, may be associated with optic nerve damage, vision acuity and vision fields disorders and posterior subcapsular cataract.
- During local treatment with neomycin, hypersensitivity reactions may occur, possibly delayed, which may cause irritation, burning, itching, and dermatitis.
- Treatment with corticosteroids in those diseases causing thinning of the cornea and the sclera, increases the risk for perforation.
- Viral and mycotic infections may be aggravated by steroids.

Side effects with unknown frequency (frequency can not be determined by available data)

- Hormone problems: 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")
- Blurred vision.

Talk with your doctor or pharmacist if you notice other effects not listed above.

5. HOW TO STORE DEXA-NEO

Keep out of the sight and reach of children.

Do not use Dexa – Neo after the expiry date which is stated on the package.

Keep in dry and cool places, at a temperature not more than 25°C.

Do not freeze.

Keep in the original package to protect from light and humidity.

6. OTHER INFORMATION

What Dexa-Neo eye drops, solution contains

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

1 ml of eye drops solution contains 1.1 mg dexamethasone sodium phosphate equivalent to 1 mg dexamethasone phosphate (0.1%) and 5 mg neomycin sulfate (0.5%).

The **excipients** are: benzalkonium chloride, sodium chloride, borax, hydrochloric acid and water for injection.

What Dexa-Neo eye ointment contains

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

1 g of eye ointment contains 0.55 mg dexamethasone sodium phosphate equivalent to 0.5 mg dexamethasone phosphate (0.05%) and 5 mg neomycin sulfate (0.5%).

The **excipients** are: white soft paraffin, liquid paraffin, cetostearyl alcohol, methyl hydroxybenzoate, hydrogenated wool fat, macrogol and water for injection.

Contents of the pack

Dexa-Neo Eye drops solution: carton box with one sterile plastic bottle of 5 ml.

Dexa-Neo Eye ointment: carton box with one sterile tube with 3.5 g.

Marketing Authorisation Holder (MAH) and Manufacturer:

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