

PACKAGE LEAFLET: INFORMATION FOR THE USER

DEXAMETHASON-NEOMYCIN

0.1% + 0.35% Ear/ eye drops, solution

Dexamethasone, neomycin

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

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1. WHAT DEXAMETHASON-NEOMYCIN IS AND WHAT IT IS USED FOR

Dexamethason-neomycin contains active substances dexamethasone and neomycin.

Neomycin belongs to the group of medicines called antibiotics. It is used to treat bacterial infections.

Dexamethasone belongs to a group of medicines called corticosteroids. Dexamethasone reduces signs of inflammation associated with bacterial infection of the eye.

The medicine is useful in the treatment of inflammatory eye diseases that respond to treatment with corticosteroids, when there is a bacterial infection, or in case of a high risk of bacterial infection of the eye.

The antibiotic neomycin, an ingredient of this medicine is active against the following pathogenic bacteria in the eye:

Staphylococcus aureus, Escherichia coli, Haemophilus influenzae, Klebsiella / Enterobacter species, Neisseria species.

Neomycin is not active enough against the following strains of bacteria: Pseudomonas aeruginosa, Serratia marcescens, streptococci including Streptococcus pneumoniae.

Dexamethason-neomycin is also used in case of inflammation of the outer ear canal, or other conditions which respond to treatment with corticosteroids, with the simultaneous need for the preventive antibiotic therapy.

2. BEFORE YOU TAKE DEXAMETHASON-NEOMYCIN

Do not take DEXAMETHASON-NEOMYCIN

- In case you are allergic (hypersensitive) to the active substance (dexamethasone or neomycin) or to any of the excipients
- If you have an eye or ear infection caused by viruses, mycobacteria (tuberculosis infection) or fungi. The medicine is used for treatment of bacterial infections.
- In the case of perforations (rupture) of the eardrum.

Take special care with DEXAMETHASON-NEOMYCIN

It is not intended for use as an injection into the eye.

Prolonged use of corticosteroids may lead to an increase in intraocular pressure and / or glaucoma with damage to the optic nerve, reduction of visual acuity and visual field defects and the appearance of cataracts (clouding of the eye lens).

Prolonged use of corticosteroids may reduce the host response to infection and increase the risk of secondary infections of the eye. In acute purulent eye diseases, corticosteroids may mask infection or extend the duration of the infection. If this medicine is used for longer than 10 days or more, intraocular (eye) pressure should be routinely monitored, even when the measurement is difficult as in children or uncooperative patients, ie Patients who do not cooperate. Caution is required during the use of corticosteroids in patients with ocular hypertension and / or glaucoma. Intraocular pressure should be often controlled. Ocular corticosteroids may prolong and worsen the current severity of many viral infections of the eye (including herpes simplex).

Neomycin sulfate can sometimes cause skin sensitization. If you encounter any skin reactions the therapy should be discontinued. One should consult a physician if redness, irritation, swelling or pain persist or worsen. The possibility of fungal infection after prolonged administration of corticosteroids should be borne in mind.

If the medicine is used for 10 or more days, one should regularly check the intraocular pressure.

Aminoglycoside antibiotics can cause partial or complete permanent deafness when administered systemically or when applied to an open wound or damaged skin. This effect is dose-dependent, and is reinforced by renal or hepatic impairment.

Patients should be instructed to avoid contact with eye droppers, eyelid, fingers, or any other surface. If the medicine is used by more than one person, it may spread the infection. When not in use, vials of the medicine should be properly closed. In addition, patients should be warned that if they improperly handle ocular preparations it can lead to contamination by bacteria which are known to cause infections of the eye. Use of contaminated products may cause serious eye damage and vision loss. If redness, irritation, swelling or pain persist or worsen, patients should consult with a doctor. Patients should also immediately consult a doctor if they need to have surgery on the eye, or have any other eye damage (eg, injury or infection).

Do not wear contact lenses during the treatment of eye infections.

One of the excipients of Dexamethason-neomycin is benzalkonium chloride which can cause eye irritation. Before instillation of drops in the eye, it is necessary to remove the contact lenses and wait at least 15 minutes before putting them again. It is known that benzalkonium chloride changes the color of soft contact lenses.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Avoid the use of any other medicine for eye disease unless you have been approved by your doctor.

If you simultaneously use multiple types of eye drops, it is necessary to make a gap of at least 5 minutes between applications of different drops.

There are no significant interactions with other medicines.

Before using the medicine Dexamethason-neomycin tell your doctor if you are taking an oral corticosteroid such as prednisone.

Pregnancy and breastfeeding

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

Your doctor will prescribe the medicine Dexamethason-neomycin, eye/ ears drops during pregnancy only if the benefit to the mother outweighs the potential risk to the fetus.

It is not known to what extent the medicine Dexamethason-neomycin passes into breast milk. If you are breastfeeding you should not use this medicine without first talking to your doctor.

If you have any further questions, please ask your doctor.

Driving and using machines

The medicine can cause transient blurred vision after the instillation of eye drops. If the vision is not clear you should not operate a motor vehicle and use machines.

Important information about some of the ingredients of Dexamethason-neomycin

Dexamethason-neomycin, eye drops contain benzalkonium chloride which can cause eye irritation and lead to a change in the color of soft contact lenses. Avoid contact with soft contact lenses. Before instillation of drops in the eye, remove contact lenses and wait at least 15 minutes before reinsertion.

If you use preparations for the eyes containing neomycin sulfate, and redness, irritation, swelling or pain persist or get worse, contact your doctor.

3. HOW TO USE DEXAMETHASON-NEOMYCIN

Always use DEXAMETHASON-NEOMYCIN exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Check before the first application of the medicine Dexamethason-neomycin drops that there was no damage to bottle closures.

Wash your hands before and after using the drops. Remove the cap from the bottle, remove the dropper from the bag and place the dropper on the bottle. Prior to application, remove the protective cover from the top of the dropper, and after the application return the protective cover on top of the dropper. Do not touch any surface (including the eye or ear) with the dropper.

The medicine is used in the eye or ear.

Eyes:

Initial Therapy: instill 1-2 drops of the solution in the affected eye every hour during the day and every two hours during the night. When you achieve the desired response you should reduce the dose to 1 drop every 4 hours. Later, further dose reduction of 1 drop 3 or 4 times a day may be enough to control the symptoms.

1. Gently throw your head back.
2. Gently pull the lower eyelid down.
3. Instill the drops in the space between the eyelid and the eye, in the area of the inner corner of the eye (near the nose).
4. Easily press the inner corner of the eye so that the liquid would empty through the tear duct.
5. Blink several times for drops to be evenly distributed.
6. Repeat the procedure on the other eye, if necessary.

Before using the drops remove contact lenses and wait at least 15 minutes before reinsertion.

Ears:

Instill 2-3 drops into the ear canal, 3 or 4 times a day.

1. Tilt the head to one side.

2. instill the drops into the ear canal.
3. Keep the head in this position for 1 to 2 minutes to allow the penetration of the drops.
4. Repeat the procedure on the other ear if necessary.

Therapy should be implemented in the smallest effective dose for the shortest possible time. Your doctor will determine the length of therapy. In the case of prolonged treatment, the application of drops should be gradually reduced in order to avoid the return of signs and symptoms of the disease.

Children

The efficacy and safety of use in children has not been established.

If you use more DEXAMETHASON-NEOMYCIN than you should

Immediately contact your doctor if you have used or swallowed a larger amount of medicine.

Signs and symptoms of overdose may include: inflammation of the cornea spot, redness, excessive tearing, swelling and itching.

In case of overdose you should rinse eyes with warm water.

If you forget to take DEXAMETHASON-NEOMYCIN

If you forgot to apply DEXAMETHASON-NEOMYCIN drops do it as soon as possible and then continue as usual. Do not apply double dose to make up for a forgotten dose.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DEXAMETHASON-NEOMYCIN can cause side effects, although not everybody gets them.

No serious side effects are expected to occur when using medicine Dexamethason-neomycin. The most common reactions that occur when using antibiotic neomycin are hypersensitivity reactions.

After applying the medicine one may experience redness, stinging, burning, tingling, itching, eye irritation, blurred vision, swollen eyelids or sensitivity to light.

There may be other side effects: increased intraocular pressure with rare optic nerve damage, cataracts (clouding of the eye lens) and slower wound healing.

When using the preparation containing corticosteroids to the eye, there were cases of acute anterior uveitis (inflammation of the iris and ciliary body), perforation of the eyeball, inflammation of the cornea and conjunctiva, ulcers on the cornea, dilated pupils, redness of the conjunctiva (conjunctiva), drooping of the upper eyelid, as well as the loss of adjustment.

With long-term use of corticosteroids there is a tendency towards the development of fungal and viral infections.

Reporting of suspected 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.

5. HOW TO STORE DEXAMETHASON-NEOMYCIN

Keep out of the reach and sight of children.

Store below 25 °C.

Dispose of the medicine 10 days after the first opening.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

The shelf life of medicine is 2 years from the date of manufacture indicated on the packaging of the medicine.

6. FURTHER INFORMATION

What DEXAMETHASON-NEOMYCIN contains

Active ingredients:

1 ml of a solution containing 1 mg of dexamethasone phosphate (in the form of dexamethasone sodium phosphate) 3.5 mg of neomycin (as neomycin sulfate)

Other ingredients:

Disodium phosphate, dihydrate; sodium dihydrogen phosphate dihydrate; sodium citrate; benzalkonium chloride; water for injections.

What DEXAMETHASON-NEOMYCIN looks like and contents of the pack

Appearance:

Dexamethason-neomycin ear/ eye drops are clear, almost colorless to pale yellow solution.

Packing:

The inner packaging is glass bottle of 10 ml. On the bottle has bromobutyl rubber fastener and aluminum cap with an arrow. After opening, dropper of low density polyethylene is placed on the bottle. The outer packaging of is folding box in which there is one bottle, dropper and patient information leaflet.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Galenika ad, Batajnički drum bb, Belgrade, Serbia