

Package leaflet: Information for the patient

NEOMDEXSOL 0.35 %/0.1 %,
Neomycine/Dexamethasone phosphate eye drops, solution

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).

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1. WHAT NEOMDEXSOL IS AND WHAT IT IS USED FOR CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION.

This medicine is an eye drops solution containing:

- an aminoglycoside bactericide antibiotic: neomycin
- and a corticosteroid: dexamethasone

This medicine is indicated for the local treatment of certain inflammation and infections of the eye:

- after eye surgery,
- in infections with inflammation caused by bacteria that are sensitive to the antibiotic contained in this medicine.

2. BEFORE YOU USE NEOMDEXSOL

Do not use NEOMDEXSOL in case of:

- allergy to the active substances or to any other components of this medicine listed in section 6.
- some inflammations of cornea (dendritic herpetic epithelial keratitis, mycosic keratitis).
- fungal or tuberculous infections of the eye.
- personal and family history of glaucoma (except if medically advised).
- early stage of viral keratoconjunctivitis.
- purulent infections of the eyelids and eyes caused by neomycin resistant microbes.

IF YOU HAVE DOUBT, ASK YOUR DOCTOR OR PHARMACIST.

Warnings and precautions

Talk to your doctor or pharmacist before using NEOMDEXSOL.

Talk to your doctor if you feel swollen and a weight gain at the level of your torso or of your face because these are the first manifestations of a syndrome called Cushing syndrome. The

inhibition of the adrenal gland function might develop after stopping a long term or intensive treatment with NEOMDEXSOL.

Talk to your doctor before stopping the treatment by yourself. These risks are of particular significance in children and patients treated with medicines called ritonavir or cobicistat. Contact your doctor in case of blurred vision or other sight disorders.

Do not swallow, do not use in periocular or intraocular injection.

In case of concurrent use with another eye drop solution, administer the eye drops with a 15-minutes interval.

In case of repeated or prolonged treatment, a significant amount can penetrate into the systemic blood flow.

Repeated or prolonged treatment can result in ocular hypertonia in some patients and/or delayed wound healing.

Tell your doctor about your current diseases, your medical history and your treatment. Do not forget to mention your allergies.

Neomycin sulfate can sometimes cause skin sensitivity: in that case, consult your doctor.

In case you do not observe any quick improvement or if unusual symptoms occur, refer to your doctor immediately.

In case of prolonged treatment, a monitoring by the ophthalmologist is required. Do not take the treatment longer than planned.

Wearing contact lenses is not recommended during the treatment.

Do not touch your eye, eyelid or any other surface with the tip of the bottle.

Put the cap back carefully after use.

Use in children: the use of this medicine should be avoided in children.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you use ritonavir or cobicistat, because these can increase the quantity of dexamethasone in your blood.

NEOMDEXSOL with food and drink

Not relevant

Pregnancy and breast-feeding

It is preferred, as a precaution, not to use NEOMDEXSOL during pregnancy.

It is preferred to avoid breast-feeding in case of prolonged treatment (more than 10 days).

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.

Sportsmen (athletes)

Warning : this specialty contains an active ingredient which may induce a positive reaction to anti-doping tests.

Driving and using machines

Not relevant

Neomdexsol contains benzalkonium chloride

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also 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.

3. HOW TO USE NEOMDEXSOL?

Posology

Apply 1 drop in the treated eye, on average 3 to 6 times per day, for 7 days.

Mode and route of administration

Eye route

- Wash your hands before any manipulation
- Tilt your head back slightly, look up and carefully pull your lower eyelid downwards.
- Squeeze the bottle and apply one drop in the lower conjunctival sac.
- Avoid contact between the tip of the bottle and your eye, eyelid or any other surface. It could get contaminated by bacteria and result in eye infections.
- Slowly close your eye.
- Put the cap back on the bottle directly after use.
- In case of concurrent use with other eye drops containing a different active substance, apply the eye drops with a 15-minute interval.

Frequency

On average 3 to 6 applications per day in the treated eye.

Duration of use

On average 7 days.

A longer treatment of an increased frequency might be prescribed under strict monitoring of an ophthalmologist.

ALWAYS STRICTLY REFER TO YOUR DOCTOR'S PRESCRIPTION

If you use more NEOMDEXSOL than you should

Repeated applications in a prolonged fashion can result in a significant systemic absorption of the active ingredients, ocular hypertension, opacification of the crystalline lens, superficial keratitis and delayed wound healing.

If you think you might have used more NEOMDEXSOL than you should and you notice side effects that are not mentioned in this leaflet, contact your doctor.

If you forgot to use NEOMDEXSOL

If you forget an application, do it as soon as possible except if it is almost time for the next dose. In this case, follow back as told by your doctor.

If you stop using NEOMDEXSOL

Not relevant.

4. POSSIBLE SIDE EFFECTS

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

- Feeling of burning, tearing, inconvenience, redness.
- Risk of allergic reactions
- In case of prolonged use: ocular hypertension, opacification of the crystalline lens, superficial keratitis and delayed wound healing.

If you get any side effects, talk to your doctor or pharmacist.

Undesirable effects reported from the data obtained after the marketing (unknown frequency):

The following undesirable effects have been observed after the marketing of the product:

- Hormonal problems: hair growth on the body (especially in women), muscle weakness and loss, purplish stretch marks (stains) on the skin, increase in arterial blood pressure, irregular or absence of menstrual periods, changes at the levels of calcium and proteins in your body, slower growth in children and adolescents and swollen and weight gain at the level of the body and the face (called “Cushing syndrome”), (see section 2 “Warnings and precautions”).
- Blurred vision.

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. You can also report side effects directly via the national reporting system.

5. HOW TO STORE NEOMDEXSOL?

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

Do not use NEOMDEXSOL after the expiry date which is stated on the carton. Do not store above 30 °C. Keep the bottle in the outer pack in order to protect from light. Do not use the eye drops for more than 30 days after first opening.

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

6. CONTENT OF THE PACK AND FURTHER INFORMATION

What does NEOMDEXSOL contain?

The active ingredients are:

Dexamethasone sodium phosphate USP equivalent to dexamethasone phosphate 0.1 % w/v.

Neomycin sulfate USP equivalent to neomycin 0.35 % w/v.

Excipients: dibasic sodium phosphate (dihydrate); edetate disodium; benzalkonium chloride; mannitol; creatinine; sodium metabisulphite; glycerine; sodium sulfoxylate formaldehyde; sodium citrate; hydrogen disodium phosphate, water for injections

What NEOMDEXSOL looks like and contents of the pack

NEOMDEXSOL eye drops, solution is available in bottle containing 5 ml of clear solution.

This leaflet was last updated in 09/2018

NEOMDEXSOL[®] is a registered trademark of Exphar s.a., Zoning Industriel Nivelles Sud, Zone II, Avenue Thomas Edison 105, 1402 Thines, Belgium

Manufactured by: Ahlcon Parenterals (I) SP-917-918, Phase-III, Ind. Area, Bhiwadi-301019, Dist. Alwar (Rajasthan) India



1. With the spike: tighten the cap on the nozzle.
2. The spike in the cap will pierce the tip of the vial
3. Dispense drops with gentle pressure. Replace the cap after every use.