TRIOMAXX

Instructions
on medical use of the drug

Trade name of the drug: Triomaxx.

INN: Dexamethasone + Neomycin + Polymyxin B.

Dosage form: Eye/ear drops.

Description: White microdispersed suspension, odorless.

Composition: 1 ml of the drug contains:
Active substances:
dexamethasone – 1.0 mg;
neomycin (in the form of sulfate) – 3.5 mg;
polymyxin B sulfate – 6000 IU;
Excipients:
hydroxypropyl methylcellulose, benzalkonium chloride, disodium edetate, sodium chloride, polysorbate 80, sodium hydroxide or hydrochloric acid, water for injection.

Pharmacotherapeutic group:
Anti-inflammatory and antibacterial agent. Dexamethasone in combination with antimicrobial drugs.

Pharmacological properties:
A combined drug with antibacterial and anti-inflammatory effects.
Dexamethasone – glucocorticosteroid drug (GCS). Does not have mineralocorticoid activity. It has a pronounced anti-inflammatory, antiallergic and desensitizing effect. Actively suppresses inflammatory processes, inhibiting the release of inflammatory mediators by eosinophils, the migration of mast cells and reducing capillary permeability.
Neomycin is a broad-spectrum antibiotic from the aminoglycoside group. It has a bactericidal effect, disrupting protein synthesis in the microbial cell. Active against gram-positive and gram-negative microorganisms, including Staphylococcus aureus, Streptococcus pneuoniae, Escherichia coli, Proteus spp., Shigella spp. Little active against Pseudomonas aeruginosa and streptococci. Inactive against pathogenic fungi, viruses, anaerobic flora. Resistance of microorganisms to neomycin develops slowly and to a small extent.
Polymyxin B is an antibiotic with a polypeptide structure. The mechanism of action is due to the ability to bind to phospholipids of microbial cell membranes, which leads to their destruction. Active against gram-negative microorganisms, including Escherichia coli, Shigella spp., Enterobacter spp., Klebsiella spp., Haemophilus influenzae, Salmonella spp., Bordetella pertussis. Highly active against Pseudomonas aeruginosa. Not active against Proteus spp., Neisseria spp., obligate anaerobes and gram-positive bacteria. Vibrio cholerae (with the exception of the eltor subtype), as well as Coccidioides immitis, are sensitive to Polymyxin B, but mostly fungi show resistance to this antibiotic.

Pharmacokinetics:
Dexamethasone: After topical application to the skin and eyes, the extent of its absorption may cause systemic effects. A significant degree of intraocular penetration of dexamethasone has been noted, which contributes to its effectiveness in inflammatory diseases of the anterior segment of the eye.
Polymyxin B sulfate: Polymyxin B sulfate is not absorbed through intact skin. Despite the fact that the intact corneal epithelium protects it from penetration into the corneal stroma, when the epithelium is damaged, therapeutic concentrations of polymyxin B penetrate into it. Significant penetration of polymyxin B sulfate into the vitreous body after parenteral or topical use of the drug has not been established.
Neomycin : After topical application, its absorption is insufficient to cause systemic side effects. There are reports of absorption through wound surfaces and inflamed skin. After absorption, neomycin is rapidly excreted through the kidneys in its active form.

Indications for use:
- blepharitis;
- conjunctivitis;
- keratitis;
- iridocyclitis;
- external otitis without perforation of the eardrum;
- infected eczema of the external auditory canal;
- acute otitis media without perforation of the tympanic membrane.

Mode of application:
Shake the bottle well before use.
During use, to prevent microbial contamination of the drug, do not touch the eye, eyelids or other surfaces with the dropper.
Before using the drops, you should warm the bottle by holding it in your hand to avoid the unpleasant sensation associated with cold liquid getting into the ear. Do not administer under pressure. Tilt your head, place the required amount of drops into your ear and keep your head tilted for several minutes.
Before prescribing the drug, it is recommended to determine the sensitivity to it of the microflora that caused the disease in the patient.

For eye diseases:

For mild forms of the disease, instill 1-2 drops into the conjunctival sac 4-6 times a day. In severe forms of the disease, drops can be used every hour, but not more than 2 days. The number of applications can be reduced to 2-3 times a day. The duration of the course of treatment is determined by the doctor individually in each individual case.

After instillation, tight eyelid closure or nasolacrimal occlusion is recommended. This reduces systemic absorption of the drug, which reduces the likelihood of systemic side effects.

For otitis externa and infected eczema of the external auditory canal, acute otitis media without perforation of the eardrum:

Adults should instill 1-5 drops into each ear 2 times a day.

The duration of treatment depends on the characteristics of the disease and is determined by the doctor.

Side effects:
Systemic side effects may occur with intensive use. Hypersensitivity reactions, often of a delayed type, are possible with topical use of neomycin.

From the immune system: hypersensitivity reactions.

On the part of the organ of vision: increased intraocular pressure with the possible subsequent development of glaucoma, the formation of posterior subcapsular cataracts, slowing down the healing process of wounds (in diseases accompanied by thinning of the cornea or sclera, breakthrough of the fibrous membrane is possible with topical use of corticosteroids, therefore it is not recommended to use Triomaxx in diseases accompanied by a defect in the corneal epithelium), keratitis, visual impairment, photophobia, mydriasis, eyelid ptosis, eye pain, eye discomfort , sensation of a foreign body in the eyes, eye irritation, increased lacrimation, conjunctivitis, keratoconjunctivitis sicca, corneal coloration, formation of scales edges of the eyelids, decreased visual acuity, corneal erosion.

From the nervous system: dysgeusia, dizziness, headache.

From the skin and subcutaneous tissue: hypersensitivity reactions, including rash, itching, irritation, swelling, redness, contact dermatitis.

The development of secondary infections can be caused by the use of combinations containing corticosteroids and antimicrobial drugs.

Secondary bacterial infection can occur as a result of suppression of the body's defense response. In acute purulent diseases of the eye, corticosteroids can mask or intensify the existing infectious process. The appearance of non-healing ulcers on the cornea after long-term use of corticosteroids may indicate the development of fungal invasion.

Contraindications: Triomaxx is contraindicated for:

- hypersensitivity to any component of the drug;

- hypersensitivity to other aminoglycosides;

- conditions after removal of a corneal foreign body;

- keratitis caused by Herpes simplex;

- viral diseases of the cornea and conjunctiva (including chicken pox);

- mycobacterial eye infections ;

- fungal and viral ear infections ;

- fungal eye diseases;

- untreated purulent eye infection;

- tuberculosis;

- existing or suspected perforation of the eardrum.

The drug is not prescribed after uncomplicated removal of a foreign body from the cornea. Topical corticosteroids should never be used for unspecified eye diseases, in particular redness of the eye, as this complicates the diagnosis of ocular pathology in the future.

Drug interactions:

The drug Triomaxx is not compatible with monomycin, streptomycin, gentamicin, amikacin , netilmicin (increased ototoxic effect). In the case of concomitant therapy with the use of other local ophthalmic drugs, an interval of 10-15 minutes should be maintained between their instillation.

Special instructions:

The drug is intended for topical use only. When using drugs containing corticosteroids for more than 10 days, intraocular pressure should be regularly measured. When using the drug Triomax simultaneously with systemic antibiotics - aminoglycosides, the concentration of neomycin in the blood serum should be monitored. It is not recommended to wear contact lenses during treatment. Avoid touching the tip of the dropper or tube to any surfaces to avoid microbial contamination of the contents of the package. The contents of the bottle of Triomaxx eye/ear drops should be shaken before use.

Use in pediatrics : Currently, the safety and effectiveness of the drug in children under 18 years of age have not been established. The drug should be stored out of the reach of children and not used after the expiration date.

During pregnancy and during lactation : not recommended.

Precautionary measures:

Before starting to use the drug, you must ensure that there is no damage to the eardrum. If the integrity of the eardrum is damaged, the use of the drug is unacceptable due to the risk of toxic effects on the auditory and vestibular apparatus (deafness, imbalance).

Local use of antibacterial drugs can cause sensitization to active substances and lead to the development of systemic reactions.

Due to the presence of a corticosteroid in the drug, the clinical picture of an allergic reaction may change. It is necessary to immediately stop using the drug if skin rashes or other local or systemic allergic reactions occur.

Athletes should be warned that the drug Triomaxx contains dexamethasone as an active ingredient , which can give a positive reaction during doping control .

If symptoms do not decrease after using the drug or if the condition worsens, the patient should consult a doctor to clarify the diagnosis and determine further treatment.

Some patients may develop hypersensitivity to locally administered aminoglycosides such as neomycin . If signs of hypersensitivity appear during use of the drug Triomaxx, treatment should be discontinued. Cross- sensitivity may occur between neomycin and other aminoglycosides for topical and/or systemic use.

With systemic use of neomycin, as well as with local application to the wound
surface or damaged skin, serious adverse reactions have been observed, including neurotoxic, ototoxic and nephrotoxic reactions. Nephrotoxic and neurotoxic reactions have also been reported with systemic use of polymyxin. B. Although there have been no reports of such reactions after topical use in ophthalmology, caution should be exercised when concomitantly prescribing systemic therapy with aminoglycosides or polymyxin B.

Long-term use of corticosteroids can lead to increased intraocular pressure and/or the development of glaucoma with subsequent damage to the optic nerve, deterioration of visual acuity, visual field defects, and the formation of posterior subcapsular cataracts. In patients with long-term use of corticosteroids (more than 10 days), intraocular pressure should be regularly monitored.

The use of corticosteroids may reduce resistance to bacterial, fungal, or viral infections, interfere with the detection of infections, and mask clinical signs of infection, preventing the detection of antibacterial failure.

If a patient develops persistent corneal ulceration, the possibility of a fungal infection should be considered. If a

fungal infection occurs, corticosteroids should be discontinued. The development of persistent corneal ulceration after long-term topical corticosteroid use may be the result of fungal invasion. If superinfection occurs, use of the drug should be discontinued and alternative therapy should be prescribed.

Since the drug contains corticosteroids, if you have diseases that lead to thinning of the cornea or sclera, the risk of perforation increases after long-term use.

When using the drug Triomaxx simultaneously with systemic antibacterial agents - aminoglycosides, it is necessary to monitor the concentration of neomycin in the blood serum. Long-term use should be avoided as it may lead to the emergence of drug-resistant microorganisms.

Topical corticosteroids should never be used in cases of undiagnosed red eye as their misuse can lead to adverse effects.

To prevent the risk of exacerbation of corneal diseases caused by the herpes virus, frequent slit-lamp examinations are recommended.

Local application of corticosteroids can mask or enhance the activity of acute purulent infectious processes of the eye.

During treatment of inflammatory or infectious processes of the eye, you should not wear contact lenses.

This product contains benzalkonium chloride, which may cause eye irritation and discoloration of soft contact lenses. Contact with soft contact lenses should be avoided. If the patient is allowed to wear contact lenses, he should be warned about the need to remove contact lenses before using the drug and wait at least 15 minutes before installing contact lenses.

Impact on the ability to drive vehicles and operate machinery:
When using any eye drops, vision may temporarily deteriorate or other visual disturbances may occur that affect the ability to drive a car or operate moving machinery. If transient visual impairment occurs after using the drug, the patient should wait until vision is restored before driving or driving machinery.

Overdose:
Currently, no cases of overdose of Triomaxx have been reported.

Release form:
Triomaxx eye/ear drops are available in 5 ml plastic bottles with a dropper stopper and a screw-on protective cap equipped with a safety ring. 1 bottle along with instructions for use in a cardboard box.

Storage conditions:
Store at a temperature not exceeding 25 °C.
After opening the bottle, use the drug within one month.

Best before date:
See packaging.

Vacation conditions:
On prescription.

Made for:
MAXX-PHARM LTD.
London, Great Britain