

GLAZADEx

Instructions

by medical application medicine

Trade name: Glazadex.

International generic name: Tobramycin + dexamethasone.

Medicinal form: Drops ophthalmic.

Compound:

Tobramycin sulfate USP eq. tobramycin 0.3% w/v;

Dexamethasone sodium phosphate USP

eq. dexamethasone 0.1% w/v;

Benzalkonium chloride solution NF

(quality preservative) 0.02% v/v;

Sterile water basis qs.

Pharmaco-therapeutic group:

aminoglycoside antibiotic, glucocorticosteroid.

Code ATX: S01CA01.

Pharmacological action:

Pharmacodynamics:

Glazadex - combined a drug with antibacterial and anti-inflammatory action for local applications v ophthalmology.

Tobramycin - an aminoglycoside antibiotic produced by *Streptococcus tenebrarius*, has a wide spectrum of antibacterial action, is active against gram-positive and gram-negative microorganisms: staphylococci (including *Staphylococcus aureus*, *Staphylococcus epidermidis*), including strains, resistant to penicillin; streptococci, including some group A beta-hemolytic species, non-hemolytic species and some *Streptococcus pneumoniae*; *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Proteus mirabilis*, *Moraxella moraxii*, majority species *Proteus vulgaris*, *Haemophilus influenzae*, *Haemophilus aegyptius*, *Moraxella lacunata*, *Acinetobacter calcoaceticus*, a also some kinds *Neisseria*.

Dexamethasone - glucocorticosteroid. It has anti-inflammatory, antiallergic and desensitizing effects. Has an antiexudative effect.

Dexamethasone actively suppresses inflammatory processes.

The combination of a glucocorticosteroid with an antibiotic (tobramycin) reduces the risk of infectious process.

Pharmacokinetics:

Dexamethasone: After topical administration of the drug, systemic absorption of dexamethasone is low. The maximum concentrati

(C max) of dexamethasone in blood plasma ranges from 220 to 888 pg / ml (about 555 ± 217 pg/ml) after applications drug by 1 drop every

eye 4 times V day V flow 2 days.

Near 77-84% dexamethasone, incoming v systemic blood flow, contacts with proteins plasma. Output by metabolism, near 60% V form

6-β- hydroxydexamethasone kidneys. Half-life amounts to average 3-4 h.

Tobramycin: After local applications drug systemic absorption tobramycin low. The concentration of tobramycin in the blood plasma

after using the drug 1 drop in each eye 4 times a day for 2 days was below threshold detection at 9 from 12 patients. With m ah tobramycin

plasma blood is 247 ng /ml. What v 8 once below threshold concentrations, associate with nephrotoxicity. Tobramycin is excreted by the

kidneys, mainly unchanged.

Indications for use:

Used to treat inflammatory diseases eyes and his appendages, caused by sensitive to pathogens:

- blepharitis;
- conjunctivitis;
- blepharconjunctivitis;
- keratitis;
- keratoconjunctivitis;
- iridocyclitis;
- prevention and treatment of inflammatory phenomena in the postoperative period after cataract extraction.

Contraindications:

- increased sensitivity to anyone from components drug;

- superficial forms keratitis, caused by Herpes simplex, in particular, tree-like keratitis;

- vaccination, wind smallpox and other viral diseases cornea and conjunctiva;

- mycobacterial infections eye;

- fungal diseases eye;

- previously not treated parasitic ocular infections;

- spicy purulent diseases organ vision without accompanying antimicrobial therapy;

- conditions after removal of a foreign body of the cornea or with defects of the corneal epithelium of another etiology;

- children's age before 12 years;

- period of breastfeeding.

With caution: deep stromal keratitis, caused by Herpes simplex; pregnancy.

Pregnancy and period lactation: Possible application for treatment pregnant women by purpose treating doctor, if the

expected therapeutic effect exceeds the risk of developing possible side effects.

Should interrupt usage drug on period feeding chest.

Directions for use and dosage:

A drug intended only for ophthalmological applications.

Before by burying thoroughly wash hands.

Before use bottle should fine shake.

For children older 12 years and adults including patients elderly age, prescribed 1-2 drops per conjunctival bag affected eyes (or eye) through

every 4-6 h.

In the first 24-48 hours, the dose can be increased to 1-2 drops into the conjunctival sac every 2 hours with a subsequent decrease in the

frequency of drug instillations as the inflammatory phenomena decrease.

Should observe caution and not stop therapy premature. In case of acute severe infectious process: 1-2 drops into the conjunctival sac

every 60 minutes until the severity of the condition decreases. Then it is necessary to reduce the frequency of drug instillations to 1-2 drops

conjunctival bag every 2 h v flow 3 days. Then by 1-2 drops to the conjunctival bag every 4 h flow 5-8 days. If necessary,

continue instillation: 1-2 drops conjunctival bag flow 5-8 days.

Prevention inflammatory phenomena v postoperative period after extraction cataracts: 1 drop into the conjunctival sac 4 times a day, starting

from the day of surgery until 24 days.

After applications drug for decrease risk development systemic side effects recommended lung pressing finger on region projections

tearful bags at internal corner of the eye v flow 1-2 min after instillation drug - this reduces systemic absorption drug. After once the bottle is

opened, use it within a month.

Side effects:

Hypersensitivity and allergic reactions (itching, swelling century, hyperemia conjunctiva).

Side effects caused by the steroid component: increased intraocular pressure; back subcapsular cataract, slowdown process healing wound

Secondary infection: Development secondary infections observed after applications combined drugs, containing

glucocorticosteroids combinations with antibiotics. Fungal infections on cornea tend to occur especially frequently with long-term use of

steroids. Appearance on the cornea non-healing ulcers after long-term treatment steroid drugs may indicate o development

fungal infestations. Secondary bacterial infection maybe arise as a result of suppression of the patient's protective reaction.

Overdose:

Symptoms: irritation of the mucous membrane of the eye, itching, lacrimation, swelling of the eyelids, conjunctival hyperemia.

Treatment: rinse eyes with warm water, symptomatic treatment.

Interaction with others medicinal means:

When used with other local ophthalmic drugs, the interval between their use should be at least 5 minutes.

If tobramycin is prescribed topically, simultaneously with systemic aminoglycoside antibiotics, the general blood picture should be

monitored.

Special instructions:

Long-term application GKS for local applications V ophthalmology, exceeding maximum recommended duration therapy - 24 day,

Maybe drive to increase intraocular pressure and development symptom complex glaucoma, including defeat visual nerve, decrease

witicism vision and narrowing borders fields vision; To education rear subcapsular cataract. That's why at patients, long-term time

applying drugs, containing GKS, should be regularly and often to measure intraocular pressure.

At development allergic reactions application drug should stop.

Bottle necessary close after everyone use.

Not should touch tip bottle to eye. Dropper bottle Glazadex in front shake when used.

Form release:

Drops ocular 10 ml PVP bottle. One bottle with instructions by application v cardboard packaging.

Conditions storage:

Store in a dry place, protected from light, at a temperature not exceeding 25 °C.

Keep out of reach for children place.

Best before date:

Specified on packaging. Not use by expiration deadline suitability.

Conditions holidays:

By recipe doctor.

Made for:

MAXX PHARM. LTD

London, Great Britain