OXIMED

Instructions
on medical use of medicinalfacilities

Trade name: Oximed.
International generic name: Moxifloxacin hydrochloride.
Medicinal form: Ophthalmic drops.
Compound:
Moxifloxacin hydrochloride USP equivalent moxifloxacin 0.5%
w/v ;
Sterile water base q. s.
Pharmacotherapeutic group:
Drugs For treatment diseases eye. Antimicrobial means – fluoroquinolone.
Code ATX: S 01 AE 07.
Pharmachologic effect:
Pharmacodynamics:
Moxifloxacin - fluoroquinolone antibacterial a drug IV generations inhibits DNA gyrase and topoisomerase IV,which bacterial cage carry out replication recombination and DNA repair. Mechanisms development resistance: Resistance to fluoroquinolone antibiotics, including moxifloxacin, develops through chromosomal mutations genes, coding DNA gyrase and topoisomerase IV. U gram-negative bacteria resistance to moxifloxacin associated with mutations system multiple resistance to antibiotics and system resistance to quinolones. Development resistance associated also with expression efflux proteins and inactivating enzymes. Cross-resistance with macrolides, aminoglycosides and tetracyclines is not expected due to differences in mechanism actions. By epidemiological data European committee by definition sensitivity to antimicrobial drugs, threshold values inhibitory concentrations moxifloxacin for various microorganisms are as follows: *Corynebacterium* no data, *Staphylococcus aureus* 0.25 mg/l, *Staphylococcus, coag - neg.* 0.25 mg/l, *Streptococcus pneumoniae* 0.5 mg/l, *Streptococcus pyogenes* 0.5 mg/l, *Streptococcus , viridansgroup* 0.5 mg/l, *Enterobacter spp*. 0.25 mg/l, *Haemophilus influenzae* 0.125 mg/l, *Klebsiella spp* . 0.25 mg/l, *Moraxella catarrhalis* 0.25 mg/l, *Morganellamorganii* 0.25 mg/l, *Neisseria gonorrhoeae* 0.032 mg/l, *Pseudomonas aeruginosa* 4 mg/l, *Serratia marcescens* 1 mg/l. Development of resistance may have significant geographical differences, a also much vary various periods time, communications with how, before the beginning therapy necessary get intelligence o resistance microorganisms specific terrain, what It hasspecial meaning treatment heavy infections, such how: often receptive kinds, aerobic gram-positivemicroorganisms: *Corynebacterium* including *Corynebacterium diphtheriae, Staphylococcus aureus* (including strains, insensitive to methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim), *Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus viridans.* Aerobic gram-negative microorganisms: *Enterobacter cloacae, Haemophilus influenzae, Klebsiella oxytoca, Moraxella catarrhalis, Serratia marcescens.* Anaerobic microorganisms: *Propionibacterium acnes*. Other microorganisms: *Chlamydia trachomatis.*
Moxifloxacin valid *in vitro* against majority below listed microorganisms, but clinical meaning thesedata unknown: Gram-positive bacteria: *Listeriamonocytogenes, Staphylococcus saprophyticus, Streptococcusagalactiae, Streptococcusmitis, Streptococcuspyogenes, Streptococcus groups C, G, F;* Gram-negative bacteria Acinetobacter baumannii, Acinetobactercalcoaceticus, Citrobacter freundii, Citrobacterkoseri, Enterobacteraerogenes, Enterobacter cloacae, Escherichia coli Klebsiellaoxytoca, Klebsiellapneumonia, Moraxella catarrhalis, Morganellamorganii, Neisseriagonorrhoeae, Proteusmirabilis, Proteus vulgaris, Pseudomonasstutzeri; Anaerobic microorganisms Clostridium perfringens,Fusobacterium spp., Prevotella spp., Propionibacterium acnes. Other microorganisms Chlamydia pneumoniae, Legionellapneumophila, Mycobacterium avium, Mycobacterium marinum, Mycoplasma pneumoniae.
Pharmacokinetics:
At local application is happening systemic suction moxifloxacin. Concentration moxifloxacin plasma wasdetermined at 21 patient male and female floor, received moxifloxacin by 1 drop 3 once a day in both eyes flow 4 days. Average maximum concentration (Cmax) moxifloxacin plasma blood in the steady state was 2.7 ng /ml, the area under the concentration-time curve (AUC) was 41.9 ng h/ml. Specified values approximately 1600 and 1200 once less, how average Cmax and AUC after reception inside therapeutic doses moxifloxacin 400 mg. Period half-life (T½) moxifloxacin amounts to near 13 h.

Indications for use:
For the treatment of inflammatory diseases of the anterior part of the eye, which were caused by microorganisms sensitive to moxifloxacin:
- Conjunctivitis;
- Corneal ulcers;
- Keratitis;
- Blepharitis;
- Dacryocystitis;
- Meibomite;
- For the prevention and treatment of bacterial eye inflammations resulting from eye injuries or after eye surgery.

Contraindications:
• individual increased sensitivity to components drug;
• children's age up to 1 year.

Pregnancy and period lactation:
Application drug at pregnancy and period breast feeding maybe case, when expected medicinal effect exceeds potential risk for fetus and child.
Animal studies have shown that following oral administration of moxifloxacin, moxifloxacin is excreted in breast milk. Small amounts of substance. However, if therapeutic doses of the drug are observed, the development ofunwanted reactions at infant children.

Way applications and doses:
A drug intended only for local applications ophthalmological practice. Not intended for applications form subconjunctival injections or for introduction front camera eyes.
Adults (including elderly patients over 65 years old) are prescribed 1 drop 3 times a day into the affected eye. Improvement state comes through 5 days carried out therapy, therapy but treatment should continue on throughout more 2-3 days.
At absence therapeutic effect through 5 days therapy recommended reconsider diagnosis and choice medicinal tactics. Duration course therapy depends from gravity state patient, clinical and bacteriological features infectious process.
Children do not require dose adjustment. Patients with hepatic and renal insufficiency correction doses not required.
To prevent microbial contamination of the tip of the bottle and the drug, it is necessary to avoid their contact with eyelids, skin of the periorbital region and other surfaces. In order to prevent absorption of the drug through the nasal mucosa must be pressed with a finger over the nasolacrimal duct for 2-3 minutes after instillation. When using several drugs for topical use in ophthalmology, the interval between their use should not be less 5 min, ocular ointments should apply last queue.

Side effects actions:
During clinical trials of moxifloxacin in dosage form for use in ophthalmology, 2252 patients received researched a drug by 1 drop right up to before 8 times/essence, 1900 from which received moxifloxacin mode by 1 drop 3 times day. Population for assessments security included 1389 patients USA and Canada, 586 patients Japan and 277 patients India. By data clinical research not received information serious unwanted phenomena how with sides organ vision, so and body in general. Most often meeting unwanted reactions, related with treatment, were irritation eye and pain eyes, total frequency occurrence these phenomena varied from 1% before 2%. In 96% of patients, the severity of these reactions was mild, while one of the patients who took part in research, severity unwanted phenomena brought to completion participation research.
On the part of the organ of vision: often - pain in the eyes, eye irritation; uncommon - punctate keratitis, dry eye syndrome, subconjunctival hemorrhage, eye itching, conjunctival injection, eyelid swelling, eye discomfort; rarely - defect corneal epithelium, corneal disorders, conjunctivitis, blepharitis, conjunctival edema, blurred vision, decreased visual acuity, asthenopia, erythema of the eyelids; frequency unknown - endophthalmitis, ulcerative keratitis, corneal erosion, increased intraocular pressure, corneal opacities, corneal edema, corneal infiltrates, corneal deposits, allergic eye phenomena, keratitis, corneal edema, photophobia, lacrimation,

discharge from the eyes, sensation foreign body eyes.

Use in children

In progress clinical research with participation children, incl. newborns, demonstrated similar with adult populationprofile security moxifloxacin form instillations. Patients age before 18 years most often were noted pain eyes and irritation eye, frequency occurrence amounted to order 0.9%. By results clinical research pediatric populations not noted differences from adult populations profile unwanted phenomena and their gravity.

Overdose:

Due to the small capacity of the conjunctival cavity, the possibility of developing a local overdose when using there are practically no drugs in the form of instillations. Total content of moxifloxacin in the drug too much few for development unwanted phenomena at random ingestion content bottle.

Interaction with other drugs:

Special research interactions moxifloxacin with others medicinal means not was carried out. In communications withlow systemic concentration after local applications as instillations interaction With others medicinalmeans unlikely.

Special instructions:

There is not enough data to make a conclusion about the effectiveness and safety of the drug Oximed treatment bacterial conjunctivitis at newborns, communications, with how application at patients this agecategories not recommended.

Oxymed is not recommended for prophylactic use or empirical treatment of gonococcal conjunctivitis in communications with availability big quantities resistant to moxifloxacin *Neisseria* strains *gonorrhoeae*. Patients with eye infections caused by *Neisseria gonorrhoeae*, must receive relevant systemic therapy.

Not recommended application drug Oximed treatment infectious diseases organ vision, caused by *Chlamydia trachomatis* in patients under 2 years of age, since there is no information on studying the drug in this category patients. Use of the drug Oxymed in patients over 2 years of age with eye diseases caused by *Chlamydia trachomatis*, must combine with systemic therapy. At availability infectious diseases front segment ocular apple not recommended wearing contact lenses.

Influence on ability manage transport means And mechanisms:

As with instillations of other medications, temporary blurred vision may occur after use drug. Before recovery clarity visual perception not recommended manage by car and others mechanisms.

Release form:

Eye drops 5 ml in a bottle. One bottle along with instructions for use in a cardboard package.

Storage conditions:

Keep dry, protected at temperature not higher 25 °C and places, inaccessible for children.

Term validity:

Specified on packaging. Not use by expiration deadline suitability.

Vacation conditions:

On prescription.

Made for:
MAXX PHARM LTD.
London, Great Britain