For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

Senzmox®-KT

Eye Drops 5ml

(Ketorolac Tromethamine & Moxifloxacin Ophthalmic Solution)

COMPOSITION:

Ketorolac Tromethamine IP ..... 0.5% w/v
Moxifloxacin Hydrochloride IP equivalent to Moxifloxacin ..... 0.5% w/v
Benzalkonium chloride Solution IP ..... 0.02% v/v
(As preservative)
Water for Injections IP ..... q.s.

Pharmacological Action

Moxifloxacin

Moxifloxacin is an 8-methoxy fluoroquinolone with a diazabicyclononyl ring at the C7 position. The antibacterial action of moxifloxacin results from inhibition of the topoisomerase II (DNA gyrase) and topoisomerase IV. DNA gyrase is an essential enzyme that is involved in the replication, transcription and repair of bacterial DNA. Topoisomerase IV is an enzyme known to play a key role in the partitioning of the chromosomal DNA during bacterial cell division.

The mechanism of action for quinolones, including moxifloxacin, is different from that of macrolides, aminoglycosides, or tetracyclines. Therefore, moxifloxacin may be active against pathogens that are resistant to these antibiotics and these antibiotics may be active against pathogens that are resistant to moxifloxacin. There is no cross-resistance between moxifloxacin and the aforementioned classes of antibiotics. Cross resistance has been observed between systemic moxifloxacin and some other quinolones.

In vitro resistance to moxifloxacin develops via multiple-step mutations. Resistance to moxifloxacin occurs in vitro at a general frequency of between 1.8 X 10-9 to <1 X 10-11 for Grampositive bacteria.

Ketorolac Tromethamine

Ketorolac Tromethamine is a nonsteroidal anti-inflammatory drug which, when administered systemically, has demonstrated analgesic, anti-inflammatory, and anti-pyretic activity. The mechanism of its action is thought to be due to its ability to inhibit prostaglandin biosynthesis. Ketorolac Tromethamine given systemically does not cause pupil constriction.

Indications: Moxifloxacin

Aerobic Gram-positive microorganisms:
Corynebacterium species *
Micrococcus luteus *
Staphylococcus aureus
Staphylococcus epidermidis
Staphylococcus haemolyticus
Staphylococcus hominis
Staphylococcus warneri
Streptococcus pneumoniae
Streptococcus viridans group

Aerobic Gram-negative microorganisms:

Acinetobacter lwoffii *
Haemophilus influenzae
Haemophilus parainfluenzae *

Other microorganisms : Chlamydia trachomatis

*Efficacy for this organism was studied in fewer than 10 infections.

The following in vitro data are also available, but their clinical significance in ophthalmic infections is unknown. The safety and effectiveness of moxifloxacin in treating ophthalmological infections due to these microorganisms have not

been established in adequate and well controlled trials.

The following organisms are considered susceptible when evaluated using systemic breakpoints. However, a correlation between the in vitro systemic breakpopint and ophthalmological efficacy has not been established. The list of organisms is provided as guidance only in assessing the potential treatment of conjunctival infections. Moxifloxacin exhibits in vitro minimal inhibitoryconcentrations(MICs) of 2 ug/ml or less (systemic susceptible breakpoint) against most (290%) of strains of the following ocular pathogens.

Aerobic Gram-positive microorganisms:

Listeria monocytogenes
Staphylococcus saprophyticus
Streptococcus agalactiae
Streptococcus mitis
Streptococcus pyogenes
Streptococcus Group C, G and F

AerobicGram-negative microorganisms:

Acinetobacter baumannii
Acinetobacter calcoaceticus
Citrobacter freundii
Citrobacter koseri
Enterobacter aerogenes
Enterobacter cloacae
Escherichia coli
Klebsiella oxytoca
Klebsiella pneumoniae
Moraxella catarrhalis
Morganella morganii
Neisseria gonorrhoeae
Proteus mirabilis
Proteus vulgaris

Anaerobic microorganisms :

Clostridium perfringens
Fusobacterium species
Prevotella species
Propionibacterium acnes

Other microorganisms :

Chlamydia pneumoniae
Legionella pneumophila
Mycobacterium avium
Mycobacterium marinum
Mycoplasma pneumoniae

Contraindications: Moxifloxacin

Moxifloxacin solution is contraindicated in patients with a history of hypersensitivity to Moxifloxacin, to other quinolones, or to any of the components in this medication.

Ketorolac Tromethamine

Ketorolac Tromethamine ophthalmic solution is contraindicated in patients with previously demonstrated hypersensitivity to any ofthe ingredients in the formulation.

Warnings

Moxifloxacin

Not for injection.

Moxifloxacin solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye. In patients receiving systematically administered quinolones,including Moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. Ifan allergic reaction to Moxifloxacin occurs, discontinue use of the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically Indicated.

Ketorolac Tromethamine

There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory agents. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs. With some nonsteroidal anti-

inflammatory drugs there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery.

Precautions

Moxifloxacin

General: As with other anti-infectives, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy and, where appropriate, fluorescein staining. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

Information for Patients

Ketorolac Tromethamine ophthalmic solution should not be administered while wearing contact lenses.

Drug Interactions:

Moxifloxacin

Pregnancy: Pregnancy Category C.

Moxifloxacin was not teratogenic when administered to pregnant rats during organogenesis at oral doses as high as 500 mg/kg/day (approximately 21 , 700 times the highest recommended total daily human ophthalmic dose); however, decreased fetal body weights and slightly delayed fetal skeletal development were observed. There was no evidence of teratogenicity when pregnant Cynomolgus monkeys were given oral doses as high as 100 mg/ky/day (approximately 4,300 times the highest recommended total daily human ophthalmic dose). An increased incidence of smaller fetuses was observed at 100 mg/kg/day. Since there are no adequate and wellcontrolled studies in pregnant women, Moxifloxacin solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactating women

Moxifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. Caution should be exercised when MOXIFLOXACIN@ solution is administered to a nursing mother.

Pediatric Use

The safety and effectiveness of moxifloxacin solution in infants below 1 year of age have not been established. There is no evidence that the ophthalmic administration of moxifloxacin has any effect on weight bearing joints, even though oral administration of some quinolones has been shown to cause arthropathy in immature animals.

Geriatric Use

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

Ketorolac Tromethamine

Pregnancy: Pregnancy Category C.

Teratogenic Effects: Pregnancy Category C: Ketorolac Tromethamine, administered during organogenesis, was not teratogenic in rabbits or rats at oral doses up to 112 times and 3 12 times the maximum recommended human topical ophthalmic dose, respectively, on a mg/kg basis assuming 100% absorption in humans and animals. When administered to rats after Day 17 of gestation at oral doses up to 46 times the maximum recommended human topical ophthalmic dose on a mg/kg basis, assuming 100% absorption in humans and animals, Ketorolac Tromethamine resulted in dystocia and increased pup mortality. There are no adequate and well-controlled studies in pregnant women. Ketorolac Tromethamine ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects

Because of the known effects of prostaglandin-inhibiting drugs on the fetal

cardiovascular system (closure of the ductus arteriosus), the use of KETOROLAC TROMETHAMINE ophthalmic solution during late pregnancy should be avoided.

Lactating women

Caution should be exercised when KETOROLAC TROMETHAMINE ophthalmic solution is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of ketorolac tromethamine in pediatric patients below the age of 3 have not been established.

Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

Adverse Reactions

Moxifloxacin

The most frequently reported ocular adverse events were conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, and tearing. These events occurred in approximately 1-6% of patients. Nonocular adverse events reported at a rate of 1-4% were fever, increased cough, infection, otitis media, pharyngitis, rash and rhinitis.

Ketorolac Tromethamine

The most frequently reported adverse reactions for Ketorolac Tromethamine ophthalmic solution occurring in approximately I to 5% of the overall study population were conjunctival hyperemia, corneal infiltrates, headache, ocular edema and ocular pain. The most frequent adverse events reported with the use of ketorolac tromethamine ophthalmic solutions have been transient stinging and burning on instillation. These events were reported by 20% - 40% of patients participating in these other clinical trials. Other adverse events occurring approximately 1% - of the time during treatment with Ketorolac Tromethamine ophthalmic solutions included allergic reactions, corneal edema, iritis, ocular inflammation, ocular irritation, ocular pain, superficial keratitis, and superficial ocular infections.

Overdose

Moxifloxacin

In the case of overdose, appropriate monitoring and management of the patient should be implemented under the care of a Physician. A topical overdose may be flushed from the eye(s) with warm tap water.

Storage Instructions

KEEP IN A COOL PLACE

PROTECT FROM LIGHT.

KEEP OUT OF REACH OF CHILDREN.

FOR EXTERNAL USE ONLY.

Presentation: Senzmox-KT is a sterile solution supplied in an opaque plastic bottle with a cap containing 5ml of solution.

Directions for use :

Turn the tamper proof cap anti-clockwise to break the seal.

Remove the cap, dispense drops with gentle pressure.

Replace the cap immediately after every use.

Manufactured in INDIA by :

Senses Pharmaceuticals Pvt. Ltd.,

No.77, 3rd Road, Bommasandra Industrial Area,
Bommasandra 4th Phase, Bengaluru - 560 099.

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