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

Moxifloxacin Ophthalmic Solution USP 0.5% w/v

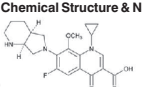
SENZMOX®

For the use of Registered Medical Practitioner only

Composition

Moxifloxacin Hydrochloride USP
equivalent to Moxifloxacin …….....……..... 0.5% w/v
Water for Injection USP……..…… q.s.

Chemical Structure & Name



(4a*S -cis*)-1-Cyclopropyl-6-fluoro-1, 4-dihydro-8-methoxy-7-(octahydro-6*H* -pyrrolo [3, 4-*b*] pyridin-6-yl)-4-oxo-3-quinolinecarboxylic acid, monohydrochloride.
1-Cyclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-[(4a*S ,7aS*)-octahydro-6*H* -pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-3-quinolinecarboxylic acid, monohydrochloride

Category

Pharmacotherapeutic group: Ophthalmologicals; anti-infectives, other anti-infectives.
ATC code: S01A E07

Description

Ophthalmic Solution.
A clear greenish yellow coloured solution free from visible particles.

Pharmacology

Moxifloxacin, a fourth-generation fluoroquinolone, inhibits the DNA gyrase and topoisomerase IV required for bacterial DNA replication, repair, and recombination.

Resistance:

Resistance to fluoroquinolones, including moxifloxacin generally occurs by chromosomal mutations in genes encoding DNA gyrase and topoisomerase IV. In Gram-negative bacteria, moxifloxacin resistance can be due to mutations in mar (multiple antibiotic resistance) and theqnr (quinolone resistance) gene systems. Resistance is also associated with expression of bacteria efflux proteins and inactivating enzymes. Cross-resistance with beta-lactams, macrolides and aminoglycosides is not expected due to differences in mode of action.
Susceptibility Testing Breakpoints
There are no pharmacological data correlated with clinical outcome for moxifloxacin administered as a topical agent.

Pharmacokinetic:

Following topical ocular administration of Moxifloxacin, it is absorbed into the systemic circulation. Plasma concentrations of moxifloxacin were measured in 21 male and female subjects who received bilateral topical ocular doses of the medicinal product 3 times a day for 4 days. The mean steady-state Cmax and AUC were 2.7 ng/ml and 41.9 ng•hr/ml, respectively. These exposure values are approximately 1,600 and 1,200 times lower than the meanCmax and AUC reported after therapeutic 400 mg oral doses of moxifloxacin. The plasma half-life of moxifloxacin was estimated to be 13 hours.

Indications

Topical treatment of purulent bacterial conjunctivitis, caused by moxifloxacin susceptible strains. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Dosage & Administration Use in adults including the elderly (≥ 65 years):The dose is one drop in the affected eye(s) 3 times a day.

The infection normally improves within 5 days and treatment should then be continued for a further 2-3 days. If no improvement is observed within 5 days of initiating therapy, the diagnosis and/or treatment should be reconsidered. The duration of treatment depends on the severity of the disorder and on the clinical and bacteriological course of infection.
Paediatric patients: No dosage adjustment is necessary.
Use in hepatic and renal impairment: No dosage adjustment is necessary.
To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip of the bottle. In order to prevent the drops from being absorbed via the nasal mucosa, particularly in newborn infants or children, the nasolacrimal ducts should be held closed for 2 to 3 minutes with the fingers after administering the drops. After cap is removed, if tamper evident snap collar is loose, remove before using the product.
If more than one topical ophthalmic medicinal product is being used, the medicinal products must be administered at least 5 minutes apart. Eye ointments should be administered last.

Method of Administration:

For ocular use only. Not for injection.
Moxifloxacin Hydrochloride 0.5%w/v eye drops, solution should not be injected subconjunctivally or introduced directly into the anterior chamber of the eye.

Contraindications

Hypersensitivity to the active substance, to other quinolones, or to any of the excipients

Warning and Precaution

In patients receiving systemically administered quinolones, 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 oedema), airway obstruction, dyspnoea, urticaria, and itching.
If an allergic reaction to Moxifloxacin occurs, discontinue use of the medicinal product.
Serious acute hypersensitivity reactions to moxifloxacin or any other product ingredient may require immediate emergency treatment. Oxygen and airway management should be administered where clinically indicated.
As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If super infection occurs, discontinue use and institute alternative therapy.
Tendon inflammation and rupture may occur with systemic fluoroquinolone therapy includingmoxifloxacin, particularly in older patients and those treated concurrently with corticosteroids. Following ophthalmic administration of Moxifloxacin plasma concentrations ofmoxifloxacin are much lower than after therapeutic oral doses of moxifloxacin, however, caution should be exercised and treatment with Moxifloxacin should be discontinued at the first sign of tendon inflammation.
Data are very limited to establish efficacy and safety of Moxifloxacin in the treatment of conjunctivitis in neonates. Therefore use of this medicinal product to treat conjunctivitis in neonates is not recommended.
Moxifloxacin should not be used for the prophylaxis or empiric treatment of gonococcal conjunctivitis, including gonococcalophthalmianeonatorum, because of the prevalence of fluoroquinolone-resistantNeisseria gonorrhoeae. Patients with eye infections caused by Neisseria gonorrhoeaeshould receive appropriate systemic treatment.
The medicinal product is not recommended for the treatment of Chlamydia trachomatis in patients less than 2 years of age as it has not been evaluated in such patients. Patients older than 2 years of age with eye infections caused by Chlamydia trachomitisshould receive appropriate systemic treatment.
Neonates with ophthalmianeonatorum should receive appropriate treatment for their condition, e.g. systemic treatment in cases caused by Chlamydia trachomitisor Neisseria gonorrhoeae.
Patients should be advised not to wear contact lenses if they have signs and symptoms of a bacterial ocular infection.
Moxifloxacin has no or negligible influence on the ability to drive and use

machines, however, as with any eye drops, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient should wait until their vision clears before driving or using machinery.

Interactions

No specific interaction studies have been performed with Moxifloxacin Hydrochloride 0.5%w/v eye drops, solution. Given the low systemic concentration of moxifloxacin following topical ocular administration of the medicinal product, drug interactions are unlikely to occur.

Pregnancy & Lactation

There are no adequate data from the use of Moxifloxacin in pregnant women. However, no effects on pregnancy are anticipated since the systemic exposure to moxifloxacin is negligible. The medicinal product can be used during pregnancy.

It is unknown whether moxifloxacin/metabolites are excreted in human milk. Animal studies have shown excretion of low levels in breast milk after oral administration of moxifloxacin.

However, at therapeutic doses of Moxifloxacin no effects on the suckling child are anticipated. The medicinal product can be used during breast-feeding.

Fertility: Studies have not been performed to evaluate the effect of ocular administration of Moxifloxacin on fertility.

Adverse reaction

The following adverse reactions are classified according to the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥ 1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) or not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in decreasing order of seriousness.

System Organ Classification	Frequency	Adverse Reactions
Blood and lymphatic system disorders	Rare	haemoglobin decreased
Immune system disorders	Not Known	hypersensitivity
Nervous system disorders	Rare	paresthesia
	Not known	Not known
Eye disorders	Common	eye pain, eye irritation
	Unknown	punctate keratitis, dry eye, conjunctivalhaemorrhage, ocular hyperaemia, eye pruritus, eyelid oedema, ocular discomfort,
	Rare	corneal epithelium defect, corneal disorder, conjunctivitis, blepharitis, eye swelling, conjunctivaloedema, vision blurred, visual acuity reduced,asthenopia, erythema of eyelid
	Not known	endophthalmitis, ulcerative keratitis, corneal erosion, corneal abrasion, intraocular pressure increased, corneal opacity, corneal infiltrates, corneal deposits, eye allergy, keratitis, corneal oedema, photophobia, eyelid oedema, lacrimation increased, eye discharge, foreign body sensation in eyes
Cardiac disorders	Not known	Palpitations

Respiratory, thoracic and mediastinal disorders	Rare	nasal discomfort, pharyngolaryngeal pain, sensation of foreign body(throat)
	Not known	dyspnoea
Gastro-intestional disorders	Uncommon	Dysgeusia
	Rare	Vomiting
	Not known	Nausea
Hepatobiliary disorders	Rare	alanine aminotransferase increased, gamma-glutamyltransferase increased
Skin and subcutaneous tissue disorders	Not known	erythema, rash, pruritus, urticarial

Description of selected adverse reactions:
Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following first dose, have been reported in patients receiving systemic quinolone therapy. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial oedema), airway obstruction, dyspnoea, urticaria and itching.
Ruptures of the shoulder, hand, Achilles, or other tendons that required surgical repair or resulted in prolonged disability have been reported in patients receiving systemic that a risk of these ruptures may be increased in patients receiving corticosteroids, especially geriatric patients and in tendons under high stress, including Achilles tendon.
Paediatric population:
Based on data from clinical trials involving paediatric patients, including neonates, the type and severity of adverse reactions in the paediatric population are similar to those in adults.
Overdosage
The limited holding capacity of the conjunctival sac for ophthalmic products practically precludes any overdosing of the medicinal product.
The total amount of moxifloxacin in a single container is too small to induce adverse effects after accidental ingestion.
Storage
Store between 15°C - 30 °C. Protect from light
Keep out of reach of children.
Shelf life
24 Months from the date of manufacture.
Presentation
A clear greenish yellow coloured solution free from visible particles filled in 5 mL Sterile Gamma-irradiated white opaque LDPE bottle sealed with Sterile Gamma-irradiated natural transparent LDPE open nozzle and Sterile Gamma-irradiated white HDPE tamp safe cap in printed carton along with leaflet.

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 :
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