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Senzmox[®]P

Eve Drops

Moxifloxacin (0.5%w/v) with

Prednisolone Acetate(1%w/v) Ophthalmic Suspension

COMPOSITION:

| Woxilloxacii i Tyurociiloride ii equivalent to Woxilloxacii | 0.076 | w/w |
|---|-------|-------|
| Prednisolone Acetate IP | 1.0 % | w/v |
| Benzalkonium Chloride Solution IP | 0.02% | 6 v/v |
| (as preservative) | | |
| Water for Injections IP | | a.s. |

Description:

Moxifloxacin and Prednisolone combination is used for the treatment of bacterial infection and inflammation of the eye.

Senzmox P Eye Drops is a prescription medicine having a combination of medicines, Moxifloxacin and Prednisolone. Moxifloxacin is an antibiotic which prevents bacterial cells from dividing and repairing, thereby killing the bacteria. This treats your infection. Prednisolone is a steroid which blocks the production of certain chemical messengers (prostaglandins) that cause redness, swelling and tiching.

Moxifloxacin Hydrochloride:

IUPAC name:1-Cyclopropyl-7-[(1S,6S)-2,8-diazabicyclo[4.3.0]nonan-8-yl]-6-fluoro-8-methoxy-4-oxoquinoline-3-carboxylic acid

Prednisolone Acetate:



IUPAC name: [2-[(8S,9S,10R,11S,13S,14S,17R)-11,17-Dihydroxy-10,13-dimethyl-3-oxo-7,8,9,11,12,14,15,16-octahydro-6H-cyclopenta[a]phenanthren-17-yl]-2-oxoethyl] acetate.

Dosage Form:

Eye Drops (Suspension)

Mechanism of Action:

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. Prednisolone acetate is a corticosteroid (anti-inflammatory agent) inhibits the edema, fibrin deposition, capillary dilation and phagocytic migration of the acute inflammatory response, as well as capillary profileration, deposition of colladen and scar formation.

Prednisolone acetate is a synthetic adrenocorticoid with the general properties of prednisolone. Adrenocorticoids diffuse across cell membranes to complex with cytoplasmic receptors and subsequently stimulate synthesis of enzymes with antiinflammatory effects. Glucocorticoids inhibit the oedema, fibrin deposition, capillary dilation and phagocytic migration of the acute inflammatory response as well as capillary proliferation. deposition of collagen and scar formation.

As directed by the Physician / Ophthalmologist

Warnings and Precautions:

The most common side effects include discomfort and irritation at the application site. If these side effects persist for a longer duration, inform your doctor. In case by accident, this medicine goes into your ears, nose or mouth, immediately rinse it with water. Inform your doctor if you are pregnant or breastfeeding or are allergic to this medicine or taking any other medication.

- Do not skip any doses and finish the full course of treatment even if you feel better. Stopping it early may make the infection come back and harder to treat.
- Do not touch the tip to any surface to avoid contamination.
- Wait for at least 5-10 minutes before delivering the next medication to avoid dilution.
- It may cause short term blurring of vision when first used. Use caution before driving or using machines.
- Do not wear contact lenses until your infection clears up.
- Do not use it more often or for longer than advised by your doctor. Inform your doctor if your condition hasn't improved after seven days of treatment.
- Make sure to use within one month of opening the bottle.

Contraindications:

Senzmox P is contraindicated in epithelial herpes simplex keratitis (Dendritic Keratitis). vaccinia, varicella, and in many other viral diseases of the conjunctiva and cornea. Mycobacterial infection of the eve and fungal diseases of ocular structures and in individuals hypersensitive to any of the components of the medication.

Use in Specific Populations:

Pregnant women:

There are no adequate and well controlled studies in pregnant women with moxifloxacin or prednisolone. Senzmox P should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Lactating women:

Caution should be exercised when Senzmox P is administered to a nursing mother.

Geriatric Population:

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

Store in a cool place . Protect from light. Keep out of reach of children. Use the Suspension within one month after opening the container.

NOT FOR INJECTION FOR EXTERNAL USE ONLY

SHAKE WELL BEFORE USE

Shelf life:

24 Months from the date of manufacture

Presentation:

Senzmox P is a off-white greenish yellow colour sterile suspension packed in a 5 mL Sterile Gamma-irradiated white opaque LDPE bottle sealed with Sterile Gammairradiated natural transparent LDPE open nozzle and Sterile Gamma-irradiated white HDPE tamp safe cap, labeled and packed in a 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 :

Senses Pharmaceuticals Pvt. Ltd.,

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

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