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

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Senzgat® P

Eye Drops

(Gatifloxacin with Prednisolone Acetate Ophthalmic Suspension(0.3% & 1% w/v))

COMPOSITION:

Gatifloxacin Sesquihydrate equivalent to Gatifloxacin ..... 0.3% w/v
Prednisolone Acetate IP ..... 1.0 % w/v
Benzalkonium Chloride Solution IP ..... 0.02% v/v
(As Preservative)
Water for Injections IP ..... q.s.

Description :

Senzgat P is a combination of gatifloxacin a fluoroquinolone antibacterial and prednisolone, a potent corticosteroid.

Pharmacodynamics:

Gatifloxacin

Gatifloxacin is an 8-methoxyfluoroquinolone with a 3-methylpiperazinyl substituent at C7. The antibacterial action of gatifloxacin results from inhibition of 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 of fluoroquinolones, including gatifloxacin, is different from that of aminoglycoside, macrolide, and tetracycline antibiotics. Therefore, gatifloxacin may be active against pathogens that are resistant to these antibiotics and these antibiotics may be active against pathogens that are resistant to gatifloxacin. There is no cross-resistance between gatifloxacin and the aforementioned classes of antibiotics. Cross-resistance has been observed between systemic gatifloxacin and some other fluoroquinolones.

Resistance to gatifloxacin in vitro develops via multiple-step mutations. Resistance to gatifloxacin in vitro occurs at a general frequency of between 1×10^{-7} to 10^{-10}.

Gatifloxacin has been shown to be active against most strains of the following organisms both in vitro and clinically, in conjunctival infections as described below:

Aerobes ,Gram-Positive

Corynebacterium propinquum*
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus mitis*
Streptococcus pneumoniae

Aerobes, Gram-Negative

Haemophilus influenzae

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

Prednisolone Acetate

Prednisolone acetate is a glucocorticoid that, on the basis of weight, has three to five times the anti-inflammatory potency of hydrocortisone. 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.

Indications

Gatifloxacin-Prednisolone ophthalmic suspension is indicated for steroid-

responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists.

Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitis is accepted to obtain a diminution in oedema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical radiation or thermal burns or penetration of foreign bodies.

Prednisolone acetate is indicated for the short-term treatment of steroid-responsive inflammatory conditions of the eyes, after excluding the presence of viral, fungal and bacterial pathogens in adults.

The use of a combination drug with an anti-infective component is indicated where the risk of infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eyes. The combination can also be used for post-operative inflammation and any other ocular inflammation associated with infection.

Drug Interactions

Gatifloxacin

Specific drug interaction studies have not been conducted with gatifloxacin ophthalmic solution. Limited information is available on the concurrent use of gatifloxacin with other ophthalmic products.

Prednisolone Acetate

None known.

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

Pregnancy

Teratogenic Effects

Pregnancy Category C

As there are no adequate and well-controlled studies in pregnant women, SENZGAT P ophthalmic suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Lactation

It is not known whether gatifloxacin-prednisolone is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when SENZGAT P ophthalmic suspension is administered to a nursing mother.

Paediatric Use

Safety and effectiveness in paediatric patients have not been established.

Geriatric Use

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

Undesirable Effects

Undesirable effects have occurred with steroid/anti-infective combination drugs, which can be attributed to the steroid component, the anti-infective component, or the combination which are described below:

Gatifloxacin

The following serious adverse reactions are

- Hypersensitivity
- Growth of Resistant Organisms with Prolonged Use
- Corneal Endothelial Cell Injury

Warnings and Precautions

General

In patients receiving systemic quinolones, including gatifloxacin, serious and, occasionally, fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angio-oedema (including laryngeal, pharyngeal or facial oedema), airway obstruction, dyspnoea, urticaria and itching. If an allergic reaction to gatifloxacin occurs, discontinue the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated. As with other anti-infectives, prolonged use may result in the overgrowth of non-susceptible organisms, including fungi. If super-infection 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.

Prolonged use of corticosteroids may result in posterior sub-capsular cataract formation and may increase intraocular pressure in susceptible individuals, resulting in glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior sub-capsular cataract formation. Prolonged use may also suppress the host immune response and, thus, increase the hazard of secondary ocular infections.

Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation.

Acute purulent infections of the eye may be masked or the activity enhanced by the presence of corticosteroid medication.

If this product is used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be checked frequently.

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

Posterior sub-capsular cataract formation has been reported after heavy or protracted use of topical ophthalmic corticosteroids.

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit-lamp microscopy is recommended.

As fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid applications and fungal invasion may be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use.

The possibility of adrenal suppression should be considered with prolonged, frequent, use of high-dose topical steroids, particularly in infants and children.

Visual Disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

The preservative in SENZGAT P ophthalmic suspension, benzalkonium

chloride, may be absorbed by and cause discoloration of soft contact lenses. Patients wearing soft contact lenses should be instructed to remove contact lenses prior to administration of the solution and wait at least 15 minutes after instilling SENZGAT P before reinserting soft contact lenses.

Effects on Ability to Drive and use Machines

There may be short-lasting blurring of vision upon instillation. If affected, the patient should not use machinery/electric tools or drive until vision has returned to normal.

STORAGE:

Keep in a cool dry place. Protect from light. Do not freeze.

KEEP OUT OF REACH OF CHILDREN.

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

SHAKE WELL BEFORE USE

Presentation

Senzgat P is a sterile suspension supplied in opaque plastic dropper bottle with a cap, containing 5 mL of the suspension.

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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