DATA SHEET

NAME OF MEDICINE
BLEPH®-10 Eye Drops
Sulfacetamide sodium 100mg/mL ophthalmic solution

PRESENTATION
Eyedrops: 10% with 1.4% polyvinyl alcohol (LIQUIFILM®), 0.005% benzalkonium chloride, polysorbate 80, sodium thiosulfate disodium edetate, dibasic sodium phosphate anhydrous, monobasic sodium phosphate heptahydrate, hydrochloric acid or sodium hydroxide to pH 7.4 and purified water.

USES
Actions: The sulfonamides are bacteriostatic agents and the spectrum of activity is similar for all. Sulfonamides inhibit bacterial synthesis of dihydrofolic acid by preventing the condensation of the pteridine with aminobenzoic acid through competitive inhibition of the enzyme dihydropteroate synthetase. Resistant strains have altered dihydropteroate synthetase with reduced affinity for sulfonamides or produce increased quantities of aminobenzoic acid.

Topically applied sulfonamides are considered active against susceptible strains of the following common bacterial eye pathogens: Escherichia coli, Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus (viridans group), Haemophilus influenzae, Klebsiella species and Enterobacter species.

Topically applied sulfonamides do not provide adequate coverage against Neisseria species, Serratia marcescens and Pseudomonas aeruginosa. A significant percentage of staphylococcal isolates are completely resistant to sulfa drugs.

INDICATIONS
Treatment of conjunctivitis, corneal ulcer, and other superficial ocular infections from susceptible micro-organisms and as an adjunct to systemic sulphonamide therapy of trachoma.

DOSAGE AND ADMINISTRATION

Conjunctivitis, corneal ulcer and superficial ocular infections:
One or two drops into lower conjunctival sac of the affected eye(s) every 2 or 3 hours during the day, less often at night.

Trachoma: 2 drops in the affected eye(s) every two hours: concomitant systemic sulphonamide therapy is indicated.

CONTRAINDICATIONS
Hypersensitivity to sulphonamide preparations. Contact lenses should not be worn in the presence of ocular infection or throughout treatment with BLEPH®-10 eye drops.
WARNINGS AND PRECAUTIONS

The solutions are incompatible with silver preparations. Non-susceptable organisms, including fungi, may proliferate with the use of this preparation. Sulfonamides are inactivated by the aminobenzoic acid present in purulent exudates.

Instructions to Patient: Note. If significant improvement of symptoms has not been achieved after 2 to 3 days of treatment, please consult your physician.

Pregnancy: Sulfonamides may cause kernicterus in babies during the first month of life by displacing bilirubin from plasma albumin. Sulfonamides should be avoided when possible in the last month of pregnancy.

Nursing Mothers: Systemically administered sulfonamides are capable of producing kernicterus in infants of lactating women. Because of the potential for the development of kernicterus in neonates, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Use in Children: Safety and effectiveness in children below the age of two months have not been established.

ADVERSE EFFECTS

Local Effects: The most common adverse reactions are conjunctival irritation, burning, and stinging. While the irritation may be transient, occasionally use of the medication has to be discontinued.

Although sensitivity reactions to sulfacetamide sodium are rare, an isolated incident of Stevens-Johnson syndrome was reported in a patient who had experienced a previous blistering drug reaction to an orally administered sulphonamide, and a single instance of local hypersensitivity was reported which progressed to a fatal syndrome resembling systemic lupus erythematous.

OVERDOSAGE

Flush excess medication from the skin with water or normal saline.

PHARMACEUTICAL PRECAUTIONS

Dropper bottles (15 mL). Protect from light and excessive heat. Do not use if solution is discoloured dark brown. Store below 25°C.

MEDICINE CLASSIFICATION

Restricted Medicine.

PACKAGE QUANTITIES

Eye Drops, 10%, 15mL.
FURTHER INFORMATION

BLEPH®-10 eye drops contains sulfacetamide sodium, polyvinyl alcohol (LIQUIFILM®), polysorbate 80, sodium thiosulfate, disodium edetate, dibasic sodium phosphate anhydrous, monobasic sodium phosphate heptahydrate and benzalkonium chloride as a preservative. The pH is maintained at 6.8 to 7.5. Sulfacetamide sodium is N-Sulfanilylacetamide monosodium salt monohydrate. Sulfacetamide sodium is soluble 1 in 2.5 of water; sparingly soluble in alcohol; practically insoluble in chloroform and ether.

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