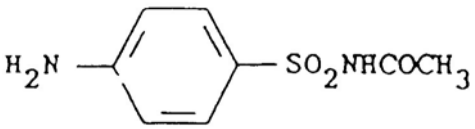
PRODUCT INFORMATION

BLEPH®-10 Eye Drops

NAME OF THE DRUG

The active constituent of BLEPH®-10 eye drops is sulfacetamide sodium.



(structure of sulfacetamide)

DESCRIPTION

Sulfacetamide sodium is a white or yellowish-white, odourless, crystalline powder. It is soluble 1 in 2.5 of water; sparingly soluble in alcohol; practically insoluble in chloroform and ether.

Chemical Name: N-Sulfanilylacetamide monosodium salt monohydrate. MW: 254.24
Empirical formula: $C_8H_9N_2NaO_3S.\ H_2O$

BLEPH®-10 eye drops are a sterile, topical anti-bacterial agent for ophthalmic use. Each mL contains sulfacetamide sodium 100 mg, polyvinyl alcohol (LIQUIFILM®), polysorbate 80, sodium thiosulfate, sodium phosphate - monobasic, disodium edetate, sodium phosphate - dibasic anhydrous and benzalkonium chloride as a preservative.

PHARMACOLOGY

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 sulfonamide therapy of trachoma.

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

PRECAUTIONS
The solutions are incompatible with silver preparations. Nonsusceptible 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: Patients should be advised to consult their physician if no significant improvement of symptoms is achieved after 2 to 3 days of treatment. Patients should not use the product if the solution is discoloured dark brown.

Carcinogenesis, mutagenesis, impairment of fertility: No studies have been conducted in animals or in humans to evaluate the possibility of these effects with ocularly administered sulfacetamide. Rats appear to be especially susceptible to the goitrogenic effects of sulfonamides and long-term oral administration of sulfonamides has resulted in thyroid malignancies in these animals.

Use in Pregnancy: Pregnancy Category C. 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.

Use in Lactation: 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.

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

ADVERSE REACTIONS
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 sulfonamide and a single instance of local hypersensitivity was reported which progressed to a fatal syndrome resembling systemic lupus erythmatosus.

OVERDOSAGE
In case of overdosage, flush the affected eye(s) with water or normal saline.

In case of oral ingestion, contact the Poisons Information Centre (telephone 13 11 26).

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

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

In order to minimise systemic absorption of BLEPH®-10 eye drops, apply pressure to the tear duct immediately following administration of the drug.

PRESENTATION
Eye Drops: 15 mL (dropper bottle).
Storage: Store below 25°C.
Shelf-life: 18 months
Protect from excessive light and heat.
To avoid contamination of the solution, keep container tightly closed.
Do not touch dropper tip to any surface.
Discard unused contents 4 weeks after opening the bottle.
Contents are sterile if seal is intact.

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