DISCLAIMER

All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akorn's Customer Service department at 800.932.5676.

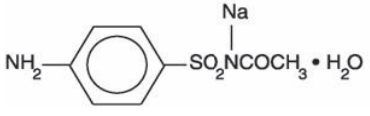
SULFACETAMIDE SODIUM
Ophthalmic Solution USP, 30%
Ophthalmic Solution USP, 10%

001202

℞ only

DESCRIPTION

Sulfacetamide Sodium Ophthalmic Solution USP is a sterile, topical anti-bacterial agent for ophthalmic use. The active ingredient is represented by the following structural formula:



Molecular Formula:
$C_8H_9\ N_2NaO_3S{\bullet}H_2O$

Molecular Weight = 254.24

Chemical name: *N*-Sulfanilylacetamide monosodium salt monohydrate.

Ophthalmic Solution 30%, Each mL contains:

Active: Sulfacetamide Sodium 300 mg. **Inactives:** Sodium Thiosulfate 1.5 mg and Monobasic Sodium Phosphate as buffer. **Preservatives:** Methylparaben 0.5 mg and Propylparaben 0.1 mg.

Ophthalmic Solution 10%, Each mL contains:

Active: Sulfacetamide Sodium 100 mg. **Inactives:** Hydroxypropyl Methylcellulose 5 mg, Sodium Thiosulfate 3.1 mg and Monobasic Sodium Phosphate as buffer. **Preservatives:** Methylparaben 0.5 mg and Propylparaben 0.1 mg.

CLINICAL PHARMACOLOGY

Microbiology: 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 AND USAGE

For the treatment of conjunctivitis and other superficial ocular infections due to susceptible microorganisms and as an adjunctive in systemic sulfonamide therapy of trachoma:

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.

CONTRAINDICATIONS

Hypersensitivity to sulfonamides or to any ingredient of the preparation.

WARNINGS

FOR TOPICAL EYE USE ONLY – NOT FOR INJECTION.

FATALITIES HAVE OCCURRED, ALTHOUGH RARELY, DUE TO SEVERE REACTIONS TO SULFONAMIDES INCLUDING STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, FULMINANT HEPATIC NECROSIS, AGRANULOCYTOSIS, APLASTIC ANEMIA AND OTHER BLOOD DYSCRASIAS. Sensitizations may recur when a sulfonamide is readministered, irrespective of the route of administration. Sensitivity reactions have been reported in individuals with no prior history of sulfonamide hypersensitivity. At the first sign of hypersensitivity, skin rash or other serious reaction, discontinue use of this preparation.

PRECAUTIONS

General: Prolonged use of topical anti-bacterial agents may give rise to overgrowth of nonsusceptible organisms including fungi. Bacterial resistance to sulfonamides may also develop.

Ophthlamic ointments may retard corneal wound healing.

The effectiveness of sulfonamides may be reduced by the para-aminobenzoic acid present in purulent exudates.

Sensitization may recur when a sulfonamide is readministered irrespective of the route of administration, and cross-sensitivity between different sulfonamides may occur.

At the first sign of hypersensitivity, increase in purulent discharge, or aggravation of inflammation or pain, the patient should discontinue use of the medication and consult a physician (see WARNINGS).

Information for patients: To avoid contamination, do not touch tip of container to eye, eyelid or any surface.

Drug Interactions: Sulfacetamide preparations are incompatible with silver preparations.

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.

Pregnancy: Pregnancy Category C. Animal reproduction studies have not been conducted with sulfonamide ophthalmic preparations. Kernicterus may occur in the newborn as a result of treatment of a pregnant woman at term with orally administered sulfonamides. There are no adequate and well controlled studies of sulfonamide ophthalmic preparations in pregnant women and it is not known whether topically applied sulfonamides can cause fetal harm when administered to a pregnant woman. This product should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

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.

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

ADVERSE REACTIONS

Bacterial and fungal corneal ulcers have developed during treatment with sulfonamide ophthalmic preparations.

The most frequently reported reactions are local irritation, stinging and burning. Less commonly reported reactions include non-specific conjunctivitis, conjunctival hyperemia, secondary infections and allergic reactions.

Fatalities have occurred, although rarely, due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias (see WARNINGS).

DOSAGE AND ADMINISTRATION

For conjunctivitis and other superficial ocular infections:

Solution: Instill one or two drops into the conjunctival sac(s) of the affected eye(s) every two to three hours initially. Dosages may be tapered by increasing the time interval between doses as the condition responds. The usual duration of treatment is seven to ten days.

For Trachoma:

Solution: Instill two drops into the conjunctival sac(s) of the affected eye(s) every two hours. Topical administration must be accompanied by systemic administration.

HOW SUPPLIED

Sulfacetamide Sodium Ophthalmic Solution, USP 30%

NDC 17478-242-12 15 mL dropper bottle, box of one.

Sulfacetamide Sodium Ophthalmic Solution, USP 10%

NDC 17478-221-12 15 mL dropper bottle, box of one.

STORAGE: Store between 2° and 30°C (36° to 86°F). **Store away from heat.**

Sulfonamide solution, on long standing will darken in color and should be discarded.

AKORN

Manufactured by: **Akorn, Inc.**
Lake Forest, IL 60045

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