SULFACETAMIDE SODIUM- sulfacetamide sodium solution/ drops
RPK Pharmaceuticals, Inc.

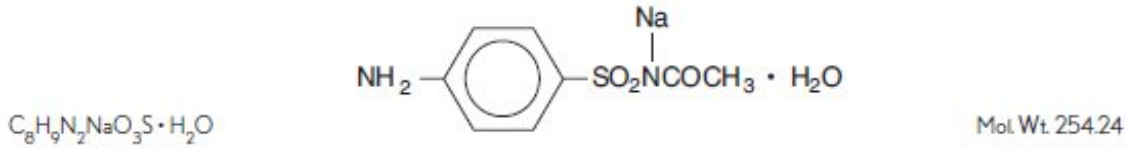
Sulfacetamide Sodium
Ophthalmic Solution, USP 10%
(Sterile)

Rx only

FOR TOPICAL EYE USE ONLY

DESCRIPTION

Sulfacetamide Sodium Ophthalmic Solution, USP 10% is a sterile, topical antibacterial agent for ophthalmic use. The active ingredient is represented by the following structural formula:



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

Each mL contains:

ACTIVE: Sulfacetamide Sodium, 100 mg/mL (10%);

INACTIVES: Methylcellulose, Purified Water, Sodium Thiosulfate. Sodium Phosphate Monobasic may be added to adjust pH (6.8-8.0).

PRESERVATIVES ADDED: Methylparaben 0.05% and Propylparaben 0.01%. The osmolality range is 700-1300 mOsm/kg.

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

Sulfacetamide Sodium Ophthalmic Solution, USP 10% is indicated 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

Sulfacetamide Sodium Ophthalmic Solution, USP 10% is contraindicated in individuals who have a 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 antibacterial agents may give rise to overgrowth of nonsusceptible organisms including fungi. Bacterial resistance to sulfonamides may also develop.

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 the 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

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 infants 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**).

To report SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb

Incorporated at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

For conjunctivitis and other superficial ocular infections: 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: 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

Product: 53002-9010

NDC: 53002-9010-3 15 mL in a BOTTLE, DROPPER

SULFACETAMIDE SODIUM SOLUTION/ DROPS

SULFACETAMIDE SODIUM

sulfacetamide sodium solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53002-9010(NDC:24208-670)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SULFACETAMIDE SODIUM (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	100 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**

METHYLCELLULOSE (100 MPA.S) (UNII: 4GFU244C4J)	
WATER (UNII: 059QF0KO0R)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53002-9010-3	15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040066	12/28/1994	

Labeler - RPK Pharmaceuticals, Inc. (147096275)

Establishment

Name	Address	ID/FEI	Business Operations
RPK Pharmaceuticals, Inc.		147096275	RELABEL(53002-9010) , REPACK(53002-9010)

Revised: 6/2023 RPK Pharmaceuticals, Inc.