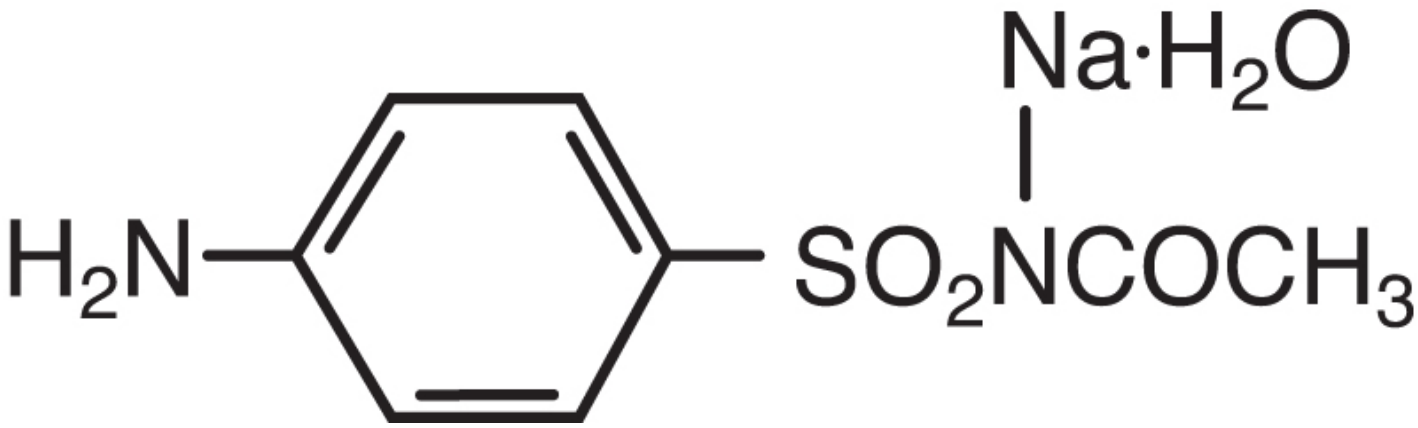
SULFACETAMIDE SODIUM- sulfacetamide sodium solution
Redpharm Drug

SULFACETAMIDE SODIUM OPHTHALMIC SOLUTION USP, 10%

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



$C_8H_9N_2Na0_3S \bullet H_2O$

MW = 254.24

Chemical Name:

N-Sulfanilylacetamide monosodium salt monohydrate.

Contains:

Active:sulfacetamide sodium 10% (100 mg/mL).

Preservative:methylparaben and propylparaben

Inactives:sodium thiosulfate, methylcellulose, and monobasic sodium phosphate

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 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: 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: Systematically 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:

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: Sulfacetamide Sodium Ophthalmic Solution USP, 10% is supplied sterile in plastic bottles in the following sizes:

15 mL: **NDC 61314-701-01**

Note: Store between 8°-25°C (46°-77°F). Protect from light. Sulfonamide solutions, on long standing, will darken in color and should be discarded.

Rx Only

Manufactured by
Alcon Laboratories, Inc.
Fort Worth, Texas 76134 for
Sandoz Inc.
Princeton, NJ 08540
Rev. August 2021
300049863-0821

PRINCIPAL DISPLAY PANEL

NDC61314-701-01
Sulfacetamide
Sodium
Ophthalmic
Solution, USP
10%
Rx Only
STERILE
15 mL
SANDOZ

SULFACETAMIDE SODIUM

sulfacetamide sodium solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:67296-0403(NDC:61314-701)
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
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
METHYLCELLULOSE (4000 MPA.S) (UNII: MRJ667KA5E)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296-0403-1	15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/25/2003	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA089560	03/25/2003	

Labeler - Redpharm Drug (828374897)

Establishment

Name	Address	ID/FEI	Business Operations
Redpharm Drug		828374897	repack(67296-0403)

Revised: 6/2024 Redpharm Drug