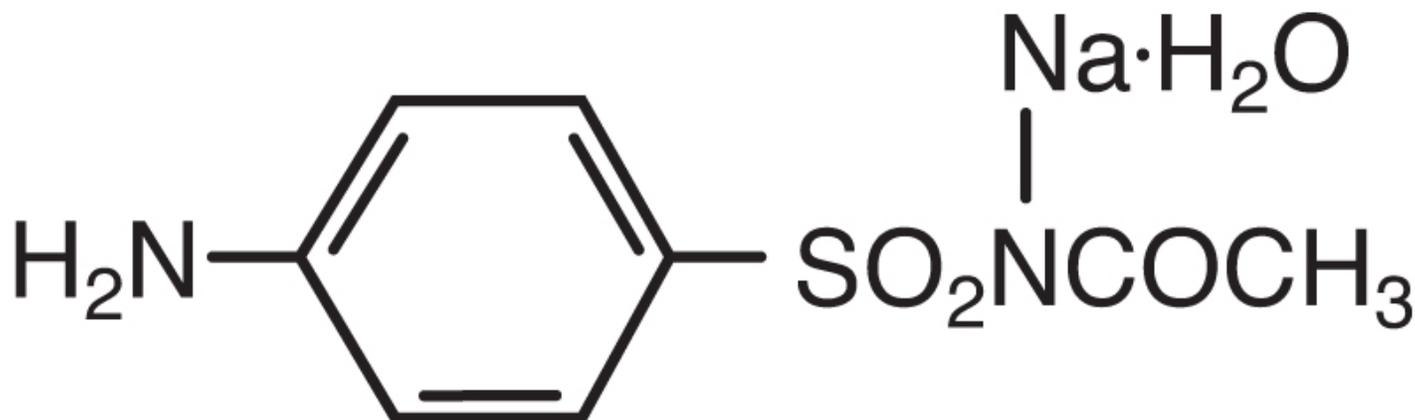


SULFACETAMIDE SODIUM - sulfacetamide sodium solution
H.J. Harkins Company, Inc.

SULFACETAMIDE SODIUM OPHTHALMIC SOLUTION USP, 10%

DESCRIPTION

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



$C_8H_9N_2NaO_3S \cdot H_2O$

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

Dist. by:

FALCON Pharmaceuticals, Ltd

Fort Worth, Texas 76134

Mfd. by:

ALCON LABORATORIES, INC.

Fort Worth, Texas 76134

Printed in USA

340192-1102

PRINCIPAL DISPLAY PANEL

NDC 61314-701-01 Rx Only

FALCON PHARMACEUTICALS®

Sulfacetamide

Sodium

Ophthalmic

Solution USP

10%

15 mL STERILE

AFFILIATE OF

ALCON LABORATORIES, INC.

QUALITY RX

Repacked by:

H.J. Harkins Company, Inc.

Nipomo, CA 93444

52959-117-01

RX Only: #XXXXXXXX

#XXX

CAUTION: Federal law PROHIBITS the transfer of this drug to anyone other than the person to whom prescribed and prohibits dispensing without a prescription unless OTC. See outsert for add'l RX info KEEP OUT OF REACH OF CHILDREN. Store in a cool dry place 68 to 77 degrees F.

SULFACET. SOD. 10% OPTH SOL

Lot #: SOS22FC

Mfg: FALCON

Exp: 04/09

Mfg Fort Worth,

Loc.: TX

Compare to: Sod.Sulamyd

Mfg. NDC: 61314-701-01

Pill ID:

SULFACET. SOD. 10% OPTH SOL
52959-117-01 Qty 15ml
04/09 Lot SOS22FC
Sod.Sulamyd 61314-701-01

SULFACET. SOD. 10% OPTH SOL
52959-117-01 Qty 15ml
04/09 Lot SOS22FC
Sod.Sulamyd 61314-701-01

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SULFACET. SOD. 10% OPTH SOL
52959-117-01 Qty 15ml
04/09 Lot SOS22FC
Sod.Sulamyd 61314-701-01

Take as directed by your Doctor or
See outsert for usual dosage information

Repack: HJ Harkins Co., Inc. Nipomo, CA 93444
Dispense in tight, child & light-resistant container per USP

SULFACETAMIDE SODIUM

sulfacetamide sodium solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52959-117(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 CPS) (UNII: MRJ667KA5E)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-117-01	15 mL in 1 BOTTLE, PLASTIC		

Marketing Information

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

Labeler - H.J. Harkins Company, Inc. (147681894)

Registrant - Falcon Pharmaceuticals, Ltd. (874345820)

Establishment

Name	Address	ID/FEI	Business Operations
Alcon Laboratories, Inc.		008018525	MANUFACTURE

Revised: 11/2011

H.J. Harkins Company, Inc.