SULFACETAMIDE SODIUM- sulfacetamide sodium ointment
Padagis US LLC

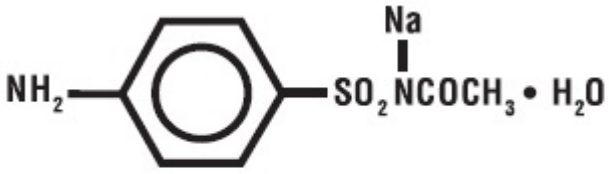
Sulfacetamide Sodium Ophthalmic Ointment USP, 10%

STERILE

Rx Only

DESCRIPTION:

Sulfacetamide Sodium Ointment USP, 10%, is a sterile, topical anti-bacterial agent for ophthalmic use. Each gram contains Sulfacetamide Sodium USP, 100 mg in an ointment base of white petrolatum and mineral oil. Sulfacetamide sodium is an odorless, white, crystalline powder. It is freely soluble in water, sparingly soluble in alcohol, and practically insoluble in benzene, chloroform, and ether. Chemically it is *N*-sulfanilylacetamide monosodium salt monohydrate, and is represented by the following structural formula:



Molecular Formula: $C_8H_9N_2NaO_3S \bullet H_2O$ Molecular Weight 254.24

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 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 aeroginosa*. 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:

Escherichia coli, Staphylococcus aureus, Staphylococcus pneumonia, 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 aeroginosa*. 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.

Ophthalmic ointments may retard corneal wound healing.

The effectiveness of sulfonamides may be reduced by the para-aminobenzoic acid present in the 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:

Teratorgenic effects.

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 been 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 *Perrigo at 1-866-634-9120*, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION:

For conjunctivitis and other superficial ocular Infections: Apply a small amount (approximately one-half inch ribbon) into the conjunctival sac(s) of the affected eye(s) every three to four hours and at bedtime. Dosages may be tapered by increasing the time interval between doses as the condition responds. The ointment may be used as adjunct to the solution. The usual duration of treatment is seven to ten days.

HOW SUPPLIED:

Sulfacetamide Sodium Ophthalmic Ointment USP, 10%, is supplied in 3.5 gram (1/8 oz) sterile, tamper evident tubes, NDC 0574-**4190**-35

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Manufactured For

Perrigo®

Minneapolis, MN

55427

1Z700 RC J1

Rev 09-13 A

R0913

Ini 0913

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL - Carton

Rx Only

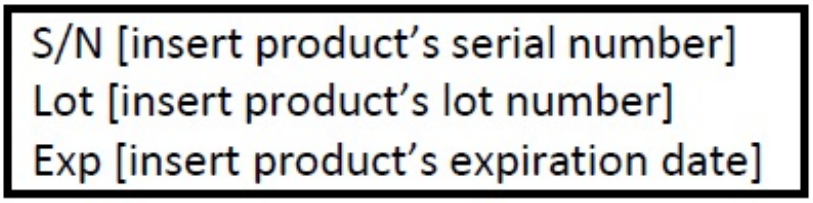
NDC 0574-**4190**-35

STERILE

Sulfacetamide Sodium Ophthalmic Ointment USP, 10%

NET WT 3.5 g (1/8 oz)

The following image is a placeholder representing the product identifier that is either affixed or imprinted on the drug package label during the packaging operation



SULFACETAMIDE SODIUM sulfacetamide sodium ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0574-4190
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 g

Inactive Ingredients	
Ingredient Name	**Strength**
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0574-4190-35	1 in 1 CARTON	08/13/2014	
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
ANDA	ANDA080029	08/13/2014	

Labeler - Padagis US LLC (967694121)

Revised: 12/2021 Padagis US LLC