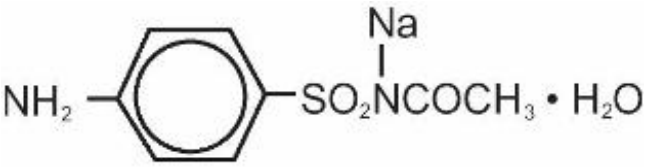
ISOPTO CETAMIDE- sulfacetamide sodium solution/ drops
CETAMIDE- sulfacetamide sodium ointment
Alcon

DESCRIPTION

ISOPTO CETAMIDE® (sulfacetamide sodium ophthalmic solution USP) 15% and CETAMIDE™ (sulfacetamide sodium ophthalmic ointment, USP) 10% are sterile topical antibacterial agents for ophthalmic use. The active ingredient is represented by the following structural formula:



Chemical name: N-Sulfanilylacetamide monosodium salt monohydrate.

Each mL of solution contains: **Active**: Sulfacetamide sodium 15% (150 mg/mL). **Preservative:** Methylparaben 0.05%, Propylparaben 0.01%. **Vehicle:** 0.5% Hydroxyporpyl Methylcellulose 2910 (viscosity type, 4000 cps). **Inactive:** Sodium Thiosulfate 0.3%, Dibasic Sodium Phosphate and/or Monobasic Sodium Phosphate (to adjust pH), Purified Water.

pH range between 7.0 and 7.8 DM-02

Each gram of ointment contains: Active: Sulfacetamide Sodium 10% (100 mg). **Preservatives:** Methylparaben 0.05%, Propylparaben 0.01%. **Inactive:** White Petrolatum, Anhydrous Liquid Lanolin, Mineral Oil. DM-00

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

Solution

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.

Ointment

For the treatment of conjunctivitis and other superficial ocular infections due to susceptible microorganisms. 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. Ophthalmic 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. 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 pediatric patients 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.

Ointment: 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 to apply CETAMIDE™ Ointment:

1. Tilt your head back.
2. Place a finger on your cheek just under your eye and gently pull down until a “V” pocket is formed between your eyeball and your lower lid.
3. Place a small amount (about ½ inch) of CETAMIDE™ Ointment in the “V” pocket. Do not let the tip of the tube touch your eye.
4. Look downward before closing your eye.

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

Solution in 5mL and 15mL plastic DROP-TAINER® Dispensers. Ointment in 3.5g ophthalmic tubes:

5 mL solution - NDC 0998-0522-05

15 mL solution - NDC 0998-0522-15

3.5 g ointment - NDC 0065-0526-35

STORAGE

Solution – Store at 8° - 24°C (46° - 75°F). Protect from light. Do not use if solution is discolored (dark brown). Sulfonamide solutions, on long standing, will darken in color and should be discarded.

Ointment – Store at 8° - 27°C (46°-80°F).

CAUTION: Federal (USA) law prohibits dispensing without prescription.

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Rev: January 1995

Alcon®

OPHTHALMIC

ALCON LABORATORIES, INC.

Fort Worth, TX 76134 USA

Printed in USA

ISOPTO CETAMIDE

sulfacetamide sodium solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0998-0522
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
sulfacetamide sodium (UNII: 4NRT660KJQ) (sulfacetamide - UNII:4965G3J0F5)		150 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
hydroxypropyl methylcellulose 2910 ()	
sodium thiosulfate (UNII: HX1032V43M)	
dibasic sodium phosphate (UNII: GR686LBA74)	
monobasic sodium phosphate (UNII: 3980JIH2SW)	
water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0998-0522-05	5 mL in 1 BOTTLE, PLASTIC		
2	NDC:0998-0522-15	15 mL in 1 BOTTLE, PLASTIC		

CETAMIDE

sulfacetamide sodium ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0065-0526
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
sulfacetamide sodium (UNII: 4NRT660KJQ) (sulfacetamide - UNII:4965G3J0F5)		100 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
white petrolatum (UNII: 4T6H12BN9U)	
anhydrous liquid lanolin ()	
mineral oil ()	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0065-0526-35	3.5 g in 1 TUBE		

Labeler - Alcon

Revised: 11/2006 Alcon