Sulfacetamide Sodium and Prednisolone Sodium Phosphate
Ophthalmic Solution 10%/0.23% (prednisolone phosphate) (Sterile)

Rx only

DESCRIPTION
Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution is a sterile topical ophthalmic solution containing an anti-infective and an anti-inflammatory agent.

Each mL contains: Sulfacetamide Sodium 100 mg, Prednisolone Sodium Phosphate 2.5 mg (equivalent to Prednisolone Phosphate 2.2 mg). INACTIVE: Poloxamer 407, Basic Acid, Estanol Dodecanol, Purified Water. Hydrochloric Acid and/or Sodium Hydroxide may be used to adjust pH (6.5-7.5). PRESERVATIVES ADDED: Thimerosal 0.001%.

The chemical name for sulfacetamide sodium is 4-Amino-3-hydroxy-5-sulfophenylacetamide dihydrochloride. The chemical name for prednisolone sodium phosphate is 11b-hydroxy-17a-pregn-4-en-21-one-3,20-dione, 21-[(2-hydroxypropyl)phosphoryl] (prednisolone phosphate) (Sterile). The molecular formula of this product is C_{32}H_{38}Cl_{2}N_{2}O_{12}P_{2}.

CLINICAL PHARMACOLOGY
Corticosteroids suppress the inflammatory response in a variety of agents and are probably delay or slow healing. Since corticosteroids may inhibit the body's defense mechanism against infection, a concurrent anti-infective drug may be used when this inhibition is considered to be clinically significant in a particular case.

When decisions to administer both a corticosteroid and an anti-infective in a topical form, the administration of such drugs in combination has the advantage of greater patient compliance and convenience, with the added assurance that the appropriate dosage of both drugs is administered, plus assured compatibility of ingredients when both types of drugs are in the same formulation and, particularly, that the correct amount of drug is delivered and retained.

The relative potency of a corticosteroid depends on the molecular structure, concentration, and vehicle from the vehicle.

Microbiology
Sulfacetamide sodium exerts a bacteriostatic effect against susceptible bacteria by restricting the synthesis of folic acid required for growth through competition with p-aminobenzoic acid. Some strains of bacteria may be resistant to sulfacetamide or susceptible strains may emerge in vivo.

The anti-inflammatory component in Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution is included to provide action against specific organisms susceptible to it. Sulfacetamide sodium is active in vitro against susceptible strains of the following microorganisms: Escherichia coli, Staphylococcus aureus, Staphylococcus (tissue group), Hemophilus influenzae, Klebsiella pneumoniae, and Enterobacter species. The product does not have adequate coverage against: Neisseria species, Pseudomonas aeruginosa (see INDICATIONS AND USAGE).

INDICATIONS AND USAGE
Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution is used orally for corticosteroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated where superficial bacterial ocular infection or risk of bacterial ocular infection exists.

Ocular corticosteroids are indicated in inflammatory conditions of the eyelid and bulbar conjunctiva, cornea, and anterior segment of the globe where the inherent risk of corticosteroid use in certain infectious conjunctivitis is acceptable to obtain diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal erosion from chemical, radiation, or thermal burns or penetration of foreign bodies.

The use of a combination drug as an anti-inflammatory component is indicated where the risk of superficial ocular infection is high or where there is an appreciation that potentially dangerous numbers of bacteria will be present in the eye.

The particular anti-inflammatory drug in the product is active against the following common bacterial eye pathogens: Neisseria species (see INDICATIONS AND USAGE), Haemophilus influenzae, Pseudomonas aeruginosa (see INDICATIONS AND USAGE), Staphylococcus (tissue group), and other sensitive bacterial species. Sulfacetamide sodium is active against the following pathogens: Staphylococcus aureus, Enterobacter species, Neisseria species, Pseudomonas aeruginosa. This product does not provide adequate coverage against: Neisseria species, Pseudomonas aeruginosa.

A significant percentage of staphylococcal isolates are completely resistant to sulfone drugs.

CONTRAINDICATIONS
Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution is contraindicated in most viral diseases of the cornea and conjunctiva, including herpes simplex keratitis, herpetic epithelial keratitis, stromal keratitis, and vernal keratoconjunctivitis, and in intraocular ocular infections of the eye and fungal diseases of ocular structures. This product is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation or to sulfonamides, or its to corticosteroids (hypoallergenicity to the antemically components occurs at a higher rate for other component).

WARNINGS
NOT FOR INJECTION INTO THE EYE
Prolonged use of corticosteroids may result in serious hypertensive glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation.

Acute anterior uveitis may occur in susceptible individuals, particularly Blacks.

Prolonged use of Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution may suppress the host's immune response and thus increase the risk of secondary ocular infections. In these cases a worsening of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids. In severe punctate conditions of the eye, corticosteroids may mask infection or exacerbate existing infections.

If this product is used for 10 days or longer, intracocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients. Corticosteroids should be discontinued in the presence of glaucoma.

Intracocular pressure should be checked frequently.

The use of corticosteroids after cataract surgery may delay healing and increase the incidence of filtering blebs.

Some strains of bacteria may be resistant to sulfacetamide or resistant strains may emerge in vivo. The chemical name for sulfacetamide sodium is 4-Amino-3-hydroxy-5-sulfophenylacetamide dihydrochloride. The chemical name for prednisolone sodium phosphate is 11b-hydroxy-17a-pregn-4-en-21-one-3,20-dione, 21-[(2-hydroxypropyl)phosphoryl] (prednisolone phosphate) (Sterile). The molecular formula of this product is C_{32}H_{38}Cl_{2}N_{2}O_{12}P_{2}.

It is possible that fungal reactions of the cornea should be considered after prolonged corticosteroid dosing. Fungal cultures should be taken when appropriate.

The p-sulfonamido group present in this ophthalmic preparation may allow sulfonamides and can reduce their effectiveness.

Sulfonamide solutions damage on prolonged standing exposure to heat and light. Do not use if solution has darkened. Yellowning does not affect activity.
Information for Patients

If information or packs larger than 48 hours or become aggravated, the patient should be advised to discontinue use of the medication and consult a physician. This product contains sodium. In some patients, edema may occur, especially when it is applied to the eyelids or other facial areas. The use of this medication by more than one person may spread infection. Keep bottle tightly closed when not in use. Protect from high, Saudi sunlight and other sources of excessive heat and light. Do not use if solution has darkened. Following does not affect activity. Keep out of the reach of children.

Laboratory Tests

Full blood counts and tests to determine the susceptibility of organisms to sulfacetamide may be indicated if signs and symptoms persist or occur in spite of the recommended course of treatment with Sodium Sulfacetamide and Prednisolone Sodium Phosphate Ophthalmic Solution.

Drug Interactions

Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution is incompatible with silver preparations. Local anesthetics related to p-aminobenzoic acid may antagonize the action of the sulfacetamide.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Prednisolone has been reported to be teratogenic. Long-term animal studies for carcinogenic potential have not been performed with prednisolone or sulfacetamide. One study detected no teratogenicity in the rabbit, hamster, and mice. In mice, prednisolone has been shown to be teratogenic when given in doses 10 to 15 times the human ocular dose. Therefore, if prednisolone and sulfacetamide are given in both eyes of pregnant mice for 10 days, the incidence of cleft palate may be observed in the fetuses of the treated mice. There are no adequate, well-controlled studies in pregnant women dosed with corticosteroids. However, teratogenicity may be precipitated in infants by sulfacetamide given systemically during the third trimester of pregnancy. It is not known whether sulfacetamide sodium can cause fetal harm when administered to a pregnant woman or whether it can affect reproductive capacity.

Sodium Sulfacetamide and Prednisolone Sodium Phosphate Ophthalmic Solution should be used during pregnancy only if the potential benefit justifies the possible risk to the fetus.

Nursing Mothers

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other adverse effects. Systemically administered corticosteroids have been shown to reduce human lactation when administered in therapeutic doses. The presence of potentiating agents in ophthalmic preparations can make the potential for systemic absorption in nursing infants from sulfacetamide sodium and prednisolone sodium phosphate ophthalmic solutions a decision that should be made whether to discontinue nursing or to discontinue the medication.

Pediatric Use

Safety and effectiveness in pediatric patients below the age of 6 years have not been established.

ADVERSE REACTIONS

Adverse reactions which have occurred with corticosteroid-anti-infective combination drugs which can be attributed to the corticosteroid component, the anti-infective component, or both are discussed. Exact incidence figures are not available since no denominator of total treated patients is available.

Reactions occurring most often from the presence of the anti-infective ingredient are allergic sensitizations. Reactions have occurred, although rarely, due to severe reactions to sulfacetamide including Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous pemphigoid, agranulocytosis, aplastic anemia, and other blood dyscrasias (see WARNINGS). Sulfacetamide sodium may cause local irritation. The reactions due to the corticosteroid component in decreasing order of frequency are: elevation of intracocular pressure (CIP) with possible development of glaucoma, and hypertensive optic nerve damage, posterior subcapsular cataract formation; and delayed wound healing.

Although systemic effects are extremely uncommon, there have been rare occurrences of systemic hypercortisolism after use of topical corticosteroids.

Sulfacetamide-containing preparations can cause acute anterior uveitis or perilimbal inflammation of the globe. Mydriasis, loss of accommodation, and pain have occasionally been reported following local use of corticosteroids.

Secondary Infection

The development of secondary infections is not infrequent after use of combinations containing corticosteroids and antimicrobials. Fungal and viral infections of the cornea are particularly prone to develop concurrently with long-term applications of corticosteroids. The possibility of fungal infections being considered a persistent corneal ulceration where corticosteroid treatment has been used.

Secondary bacterial/ocular infection following suppression of host responses also occur. To report SUSPECTED ADVERSE REACTIONS, contact Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC, 61-069-001-459% or FDA at 1-888-FDA-1088 or www.fda.gov/medwatch.

Dosage and Administration

Instill two drops of Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution topically in the eye(s) every 4 hours, or more than 20 mL should be prescribed initially. If signs and symptoms fail to improve after two days, patients should be re-evaluated (see PRECAUTIONS).

Care should be taken not to discontinue therapy prematurely. In chronic conditions, withdrawal of treatment should be carried out by gradually decreasing the frequency of application.

FOR OPHTHALMIC USE ONLY

HOW SUPPLIED

Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution 10%/0.23% (prednisolone phosphate) is supplied in a plastic bottle with a white cap and controlled drop tip in the following size:

5 mL bottle - NDC 2408-317-20
10 mL bottle - NDC 2408-317-18

DO NOT USE IF IMPERFORATED NECKBAND IS NOT INTACT

Storage: Store between 15°-25°C (59°-77°F). KEEP FROM FREEZING. PROTECT FROM LIGHT. KEEP TIGHTLY CLOSED. Sulfacetamide solutions darken on prolonged standing and exposure to heat and light. Do not use if solution has darkened. Following does not affect activity. KEEP OUT OF REACH OF CHILDREN.

Revised: July 2015
Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC
Bridgeview, NJ 08017 USA
©Bausch & Lomb Incorporated

Approved