

Sulfacetamide sodium 10% eye drops

Sulfacetamide sodium 100 mg/mL

Name of the Drug

Sulfacetamide sodium 10% eye drops is a sterile topical antibacterial agent for ophthalmic use.

Description

List of excipients

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

Preservative: sodium methyl hydroxybenzoate and sodium propyl hydroxybenzoate.

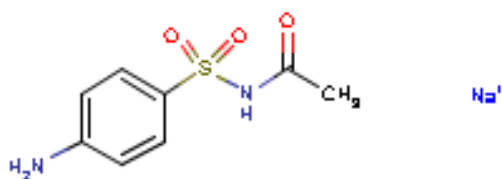
Inactive: sodium thiosulfate, methylcellulose, and sodium phosphate - monobasic.

Sulfacetamide sodium is a white or yellowish white, crystalline powder; odourless. 1.19g of sulfacetamide sodium BP is approximately equivalent to 1g of sulfacetamide.

Sulfacetamide sodium is freely soluble in water (1 in 2.5); slightly soluble in ethanol (96%); practically insoluble in chloroform and ether. A 5% solution in water has a pH of 8.0 to 9.5. Store in airtight containers. Protect from light.

When solutions are heated, hydrolysis occurs forming sulphanilamide which may be deposited as crystals, especially from concentrated solutions and under cold storage conditions.

The active ingredient is represented by the following structural formula:



Molecular weight:	254.2
Empirical formula:	C ₈ H ₉ N ₂ NaO ₃ S.H ₂ O
Chemical name:	N-Sulfanilylacetylamide monosodium salt monohydrate.

Pharmacology

Actions

Sulfonamides are usually bacteriostatic; however, in extremely high concentrations, they may be bactericidal. Sulfonamides interfere with utilization of para-aminobenzoic or para-aminobenzoic glutamic acids by bacteria, thus inhibiting the biosynthesis of folic acid which is essential for the growth of susceptible micro-organisms. Only micro-organisms that synthesize their own folic acid are inhibited by sulfonamides; animal cells and bacteria that are capable of utilizing folic acid precursors or preformed folic acid are not affected by these agents. The antibacterial activity of the sulfonamides is decreased in the presence of blood or purulent exudates which contain para-aminobenzoic acid.

Sulfonamides have a broad antimicrobial spectrum in vitro against gram-positive and gram-negative micro-organisms. 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 medicines.

Pharmacokinetics

Not available.

Indications

For the treatment of acute and chronic bacterial conjunctivitis, corneal ulcer, and other superficial ocular infections from susceptible micro-organisms, and as an adjunct to systemic sulfonamide therapy of trachoma.

Contraindications

Sulfacetamide sodium 10% eye drops is contraindicated in individuals who have a hypersensitivity to sulfonamides or to any ingredient of the preparation.

Contact lenses should not be worn in the presence of ocular infection or throughout treatment with Sulfacetamide sodium 10% eye drops.

Precautions

OPHTHALMIC USE ONLY

The solutions are incompatible with silver preparations. They are also incompatible with other eye drops due to the anionic sulfacetamide in Sulfacetamide sodium 10% eye drops which can cause precipitation if used with other eye drops, since most eye drops are cationic.

Non-susceptible micro-organisms, including fungi, may proliferate with use of this preparation. Sulfonamides are inactivated by the aminobenzoic acid present in purulent exudates.

The patient should be re-examined if significant improvement of symptoms has not been achieved after two to three days of treatment.

At the first sign of hypersensitivity, increased purulent discharge, or aggravation of inflammation or pain, the patient should discontinue use of the medication and consult a physician.

Sensitization may recur when a sulfonamide is re-administered irrespective of the route of administration, and cross-sensitivity between different sulfonamides may occur.

Drug Interactions

Sulfacetamide preparations are incompatible with silver preparations.

Use in Pregnancy

Sulfonamides cross the placenta and may cause jaundice and haemolytic anaemia in the newborn.

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.

Use in Lactation

Systemically administered sulfonamides are capable of producing kernicterus in infants of lactating mothers. Because of the potential for the development of kernicterus in neonates, a decision should be made whether to discontinue nursing or discontinue the agent, taking into account the benefit of the agent to the mother.

Use in Children

Safety and effectiveness in children below the age of two months have not been established.

Carcinogenicity, Mutagenesis, Impairment of Fertility

There are no published studies in animals or in humans that 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.

Information for patients

To avoid contamination, do not touch tip of container to the eye, eyelid or any surface. Discard unused contents 4 weeks after opening the container.

Contact lenses

Sulfacetamide sodium 10% eye drops should not be administered while wearing contact lenses. If patients continue to wear soft (hydrophilic) contact lenses while under treatment with Sulfacetamide sodium 10% eye drops they should remove their

lens(es) prior to instilling Sulfacetamide sodium 10% eye drops in the affected eye(s) and should not insert their lens(es) until 15 minutes after instillation of the eye drops.

Adverse effects

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 PRECAUTIONS).

Dosage and administration

Conjunctivitis, corneal ulcer and superficial ocular infections
Instil 1 or 2 drops into the lower conjunctival sac of the affected eye(s) every two to three hours during the day, less often at night.

Trachoma

Instil two drops in the affected eyes every two hours: concomitant systemic sulfonamide therapy is indicated.

The usual duration of treatment is seven to ten days.
The systemic absorption of Sulfacetamide sodium 10% eye drops can be minimised by applying gentle pressure on the tear duct for approximately one minute immediately after application.

Overdosage

Accidental ingestion of the agent is unlikely to cause any toxicity due to low content of the medicine. It contains low quantities of preservatives (sodium methyl hydroxybenzoate: 0.13mg/ml and sodium propyl hydroxybenzoate 0.25mg/ml). If the eye drops are accidentally ingested by infants or young children, Poisons Information Centre should be contacted. The medication should be kept out of reach of children.

Treatment

If irritation, pain, swelling, lacrimation or photophobia occur after undesired eye contact, the exposed eye(s) should be irrigated with copious amounts of room temperature water for at least 15 minutes. If symptoms persist after 15 minutes of irrigation, an ophthalmological examination should be considered.

Poison Schedule of the Drug

Restricted medicine

Presentation

Sulfacetamide Sodium Eye Drops, 10% is supplied sterile in 15mL plastic bottle.

Storage

Store below 25°C. Protect from light. Do not use if the solution is darkened.

Name and Address of Sponsor

This product is distributed in New Zealand by:

Alcon New Zealand Limited
Auckland New Zealand
Free phone: 0800 101 106

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