

Prescribing Information

Pr SODIUM SULAMYD 10%®

**sulfacetamide sodium
Ophthalmic Solution**

Antibacterial

Sandoz Canada Inc.
145, rue Jules-Léger
Boucherville, QC, Canada
J4B 7K8

Date of preparation: 18 June 2018

Control No. : 214225

Pr SODIUM SULAMYD 10%®

sulfacetamide sodium

Ophthalmic Solution

Antibacterial

PHARMACOLOGY

Sodium sulfacetamide, a bacteriostatic sulfonamide, is effective against a wide range of microorganisms, commonly associated with external ocular infections. Sodium sulfacetamide inhibits the growth of susceptible strains of *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *albus*, *Klebsiella pneumoniae*, *Escherichia coli* and *Enterobacter aerogenes*. Sodium sulfacetamide penetrates into ocular fluids and tissues in high concentration.

INDICATIONS

The treatment of conjunctivitis, corneal ulcer, and other superficial ocular infections due to susceptible microorganisms, and as adjunctive treatment in systemic therapy of trachoma.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of SODIUM SULAMYD 10% and other antibacterial drugs, SODIUM SULAMYD 10% should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

CONTRAINDICATIONS

Hypersensitivity to sulfonamide preparations.

PRECAUTIONS

The solutions are incompatible with silver preparations. Do not use solutions if coloured. Sulfonamides may be inactivated by the para-aminobenzoic acid present in purulent exudates. If sensitivity reactions occur, discontinue treatment.

Topical anesthetics derived from aminobenzoic acid may antagonize the antibacterial effect of topical sulfonamides if applied concurrently.

If prompt clinical response is not obtained with Ophthalmic Solution 10%, further evaluation is advised.

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing SODIUM SULAMYD 10% in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of resistant organisms.

Potential for Microbial Overgrowth

Prolonged use of SODIUM SULAMYD 10% may give rise to overgrowth of nonsusceptible microorganisms and fungi. If new infection occurs, discontinue use and institute alternative therapy.

Cross-sensitivity among sulfonamides may occur.

Safety and effectiveness for use in children below the age of 6 years have not been established.

The solution 10% is intended for topical application only and not for injection.

Usage in Pregnancy and Nursing Mothers: Safety during pregnancy has not been established.

ADVERSE REACTIONS

Sodium sulfacetamide may cause local irritation. Most often the reactions result from allergic sensitization. Although sensitivity reactions to sodium sulfacetamide are rare, instances of Stevens-Johnson syndrome and systemic lupus erythematosus (in one case producing a fatal outcome) have been reported following the use of ophthalmic sulfonamide preparations.

OVERDOSAGE INFORMATION

A single overdose of ophthalmic sodium sulfacetamide would not be expected to produce symptoms.

DOSAGE

10% Solution with Methylcellulose: 1 or 2 drops into the lower conjunctival sac every 2 or 3 hours during the day and less often at night.

SUPPLIED

Each mL of sterile ophthalmic solution contains: sulfacetamide sodium USP 100 mg (10% with methylcellulose USP). Nonmedicinal ingredients: hydroxypropyl methylcellulose, methylparaben, monobasic sodium phosphate, propylparaben, sodium thiosulfate and water. Plastic dropper bottles of 15 mL. Store between 2 and 30°C. Protect from light.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

SODIUM SULAMYD 10%®

Sulfacetamide sodium ophthalmic solution

Read this carefully before you start taking SODIUM SULAMYD 10% and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about SODIUM SULAMYD 10%.

What is SODIUM SULAMYD 10% used for?

SODIUM SULAMYD 10% is used in adults and children 6 years of age and older to treat eye infections caused by bacteria. It can also be used together with medicines taken by mouth to treat an eye infection called “trachoma”.

Antibacterial drugs like SODIUM SULAMYD 10% treat only bacterial infections. They do not treat viral infections.

How does SODIUM SULAMYD 10% work?

SODIUM SULAMYD 10% is an antibiotic that stops the growth of certain bacteria that can cause eye infections.

What are the ingredients in SODIUM SULAMYD 10%?

Medicinal ingredients: sulfacetamide sodium.

Non-medicinal ingredients: hydroxypropyl methylcellulose, methylparaben, monobasic sodium phosphate, propylparaben, sodium thiosulfate and water.

SODIUM SULAMYD 10% comes in the following dosage forms:

Ophthalmic solution: 100 mg/mL

Do not use SODIUM SULAMYD 10% if:

- you are allergic to sulfacetamide sodium, sulfonamide preparations or any of the other ingredients in SODIUM SULAMYD 10%.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SODIUM SULAMYD 10%. Talk about any health conditions or problems you may have, including if:

- you are pregnant.
- there is a lot of discharge or pus in your infected eye.
- you are using other topical eye drops such as silver preparations or products to numb the eye or reduce pain (anesthetics).

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take SODIUM SULAMYD 10%:

- For external use only.
- To avoid contamination, do not touch the tip of the dropper.
- Although you may feel better early in treatment, SODIUM SULAMYD 10% should be used

exactly as directed.

- Misuse or overuse of SODIUM SULAMYD 10% could lead to the growth of bacteria that will not be killed by SODIUM SULAMYD 10% (resistance). This means that SODIUM SULAMYD 10% may not work for you in the future.
- Do not share your medicine.

Usual dose:

1 or 2 drops in the affected eye every 2 to 3 hours during the day.
SODIUM SULAMYD 10% can be used less often at night.

Applying SODIUM SULAMYD 10% into the eye:

- Wash hands with soap and water.
- Tilt the head back or lie down and look toward the ceiling.
- With the eyes open, gently pull the lower eyelid below the eyelashes away from the eye to form a pouch.
- Hold the bottle at least 2 cm away and squeeze one drop into the pouch.
- Slowly release the lower lid.
- Gently close the eye for one or two minutes. Do not rub the eye and try not to blink.
- If multiple drops are needed, wait three to five minutes between each drop.
- Do not let the bottle directly touch the eye.
- Contact lenses should not be worn until the infection has resolved.

Overdose:

If you think you have taken too much SODIUM SULAMYD 10%, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using SODIUM SULAMYD 10%?

These are not all the possible side effects you may feel when taking SODIUM SULAMYD 10%.
If you experience any side effects not listed here, contact your healthcare professional.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON Local irritation: inflammation and swelling of the eyelid, pain and tearing			√
RARE Stevens-Johnson syndrome: red or purple rash, blisters on the skin and mucous membranes of the nose, mouth, eyes and genitals, peeling skin, fever, flu-like symptoms			√
Systemic lupus erythematosus: red, blotchy rash mainly on the			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
face, fatigue, fever, loss of appetite			
Allergic reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
--

Storage:

Store between 2 and 30°C. Protect from light.

Keep out of reach and sight of children.

If you want more information about SODIUM SULAMYD 10%:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website <https://www.canada.ca/en/health-canada.html>; the manufacturer’s website www.sandoz.ca, or by calling 1-800-361-3062.

This leaflet was prepared by Sandoz Canada Inc.

Last Revised: June 18, 2018