

PRESCRIBING INFORMATION

Pr ODAN-SULFACETAMIDE

Sulfacetamide Sodium Ophthalmic Solution, USP

10 %

ANTIBACTERIAL

ODAN LABORATORIES LTD.
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 **ODAN**
www.odanlab.com

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THERAPEUTIC CLASSIFICATION

Antibacterial

ACTION AND CLINICAL PHARMACOLOGY

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 sulfadruugs.

INDICATIONS

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.

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 sulfadruugs.

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

CONTRAINDICATIONS

Hypersensitivity to sulfonamides or to any ingredient of the preparation.

DRUG INTERACTIONS

Sulfacetamide preparations are incompatible with silver preparations.

PRECAUTIONS

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing ODAN-SULFACETAMIDE 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 ODAN-SULFACETAMIDE may give rise to overgrowth of nonsusceptible bacteria and fungi. Bacterial resistance to sulfonamides may also develop. Should superinfection occur during therapy, appropriate measures should be taken.

General

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).

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

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

Do not use solutions if coloured.

WARNINGS

FOR TOPICAL EYE USE ONLY – NOT FOR INJECTION.

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 WARNINGS), and systemic lupus erythematosus (in one case producing a fatal outcome).

OVERDOSAGE

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

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.

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.

AVAILABILITY

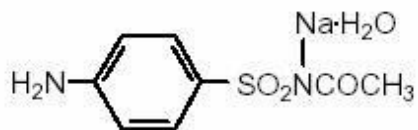
Each mL of sterile ophthalmic solution contains: Sulfacetamide Sodium 100 mg and the following non-medicinal ingredients: hydroxypropyl methylcellulose, sodium thiosulfate and monobasic sodium phosphate to adjust pH in purified water. Contains methylparaben 0.5 mg and propylparaben 0.1 mg as preservatives. Supplied as a sterile 10 % solution in 15 mL plastic dropper bottles.

STORAGE CONDITIONS

Store between 2° and 30°C. Keep container tightly closed.

PHARMACEUTICAL INFORMATION

Structural Formula:



Chemical Name: *N*-Sulfanilylacetylamide monosodium salt monohydrate

Molecular Formula: C₈H₉ N₂NaO₃S•H₂O

Molecular Weight: 254.24 g / mol

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

**Pr ODAN-SULFACETAMIDE
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Read this carefully before you start taking ODAN-SULFACETAMIDE 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 ODAN-SULFACETAMIDE.

What is ODAN-SULFACETAMIDE used for?

ODAN-SULFACETAMIDE 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 ODAN-SULFACETAMIDE treat only bacterial infections. They do not treat viral infections.

How does ODAN-SULFACETAMIDE work?

ODAN-SULFACETAMIDE is an antibiotic that stops the growth of certain bacteria that can cause eye infections.

What are the ingredients in ODAN-SULFACETAMIDE?

Medicinal ingredients: sulfacetamide sodium.

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

ODAN-SULFACETAMIDE comes in the following dosage forms:

Ophthalmic solution: 100 mg / mL

Do not use ODAN-SULFACETAMIDE if:

- You are allergic to sulfacetamide sodium, sulfonamide preparations or any of the other ingredients in ODAN-SULFACETAMIDE.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ODAN-SULFACETAMIDE. 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 ODAN-SULFACETAMIDE:

- For external use only.
- To avoid contamination, do not touch the tip of the dropper.
- Although you may feel better early in treatment, ODAN-SULFACETAMIDE should be used exactly as directed.
- Misuse or overuse of ODAN-SULFACETAMIDE could lead to the growth of bacteria that will not be killed by ODAN-SULFACETAMIDE (resistance). This means that ODAN-SULFACETAMIDE may not work for you in the future.
- Do not share your medicine.

Usual dose:

For conjunctivitis and other superficial ocular infections:

1 or 2 drops in the affected eye every 2 to 3 hours. Time between doses may be increased as condition improves.

Usual duration of treatment is 7 to 10 days.

For Trachoma as adjunct therapy: 2 drops in the affected eye every 2 hours.

Applying ODAN-SULFACETAMIDE 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 ODAN-SULFACETAMIDE, 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 ODAN-SULFACETAMIDE?

These are not all the possible side effects you may feel when taking ODAN-SULFACETAMIDE. 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 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.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- 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.

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.

Storage:

Store between 2 and 30°C. Protect from light and keep container tightly closed.

Keep out of reach and sight of children.

If you want more information about ODAN-SULFACETAMIDE:

- Talk to your healthcare professional
- Find the full Prescribing Information 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>; or by contacting the manufacturer, Odan Laboratories Limited, at 1-800-387-9342.

This leaflet was prepared by
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