

PRESCRIBING INFORMATION
INCLUDING PATIENT MEDICATION INFORMATION

Pr ODAN-CIDE

Sulfacetamide Sodium and Prednisolone Acetate Ophthalmic Suspension, USP

Sulfacetamide Sodium 10%
Prednisolone Acetate 0.5%

CORTICOSTERIOD / ANTIBACTERIAL

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THERAPEUTIC CLASSIFICATION

CORTICOSTEROID / ANTIBACTERIAL

ACTION AND CLINICAL PHARMACOLOGY

Corticosteroids suppress the inflammatory response to a variety of agents and they may delay or slow healing. Since corticosteroids may inhibit the body's defense mechanism against infection, a concomitant antimicrobial drug may be used when this inhibition is considered to be clinically significant.

The anti-infective component in the combination is included to provide action against specific organisms susceptible to it.

INDICATIONS

ODAN-CIDE is for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists. Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster, keratitis, iritis, cyclitis and selected infective conjunctivitis when the inherent risk of steroid use is accepted to obtain a diminution in edema and inflammation. Corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies is also indicated.

The use of a combination drug with an anti-infective component is indicated where the risk of infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye. The particular anti-infective drug in this product is active against the following common bacterial eye pathogens: Staphylococcus aureus, Streptococci (including streptococcus pneumonia), Escherichia coli, Hemophilus influenzae and Klebsiella enterobacter species. The product does not provide adequate coverage against Neisseria species and Serratia marcescens.

ODAN-CIDE contains an antibacterial ingredient, sulfacetamide sodium. To reduce the development of drug-resistant bacteria and maintain the effectiveness of sulfacetamide sodium,

ODAN-CIDE should only be used for the authorized indication and clinical use.

PRECAUTIONS

The possibility of fungal infections of the cornea should be considered after prolonged steroid dosing.

Susceptibility/Resistance

Development of Drug Resistant bacteria

Prescribing ODAN-CIDE in the absence of the authorized indications is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

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

WARNINGS

Extended use may result in increased intraocular pressure in susceptible individuals with damage to the optic nerve, defects in visual acuity and fields or vision. It is advisable that intraocular pressure be checked frequently. Prolonged use may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection. Prolonged use may cause posterior subcapsular cataracts. This product should be used with caution in narrow-angle glaucoma. Employment of steroid medication in the treatment of herpes simplex requires great caution.

ADVERSE REACTIONS

Adverse reactions have occurred with steroid / anti-infective combination drugs. The reactions due to the steroid component are: elevation of intraocular pressure (IOP) with possible development of glaucoma, and infrequent optic nerve damage, posterior subcapsular cataract formation; and delayed wound healing. Secondary infection: Fungal infections of the cornea are particularly prone to develop coincidentally with long-term applications of the steroid. The possibility of fungal invasion must be considered in any persistent corneal ulceration where steroid treatment has been used. Secondary bacterial ocular infection following suppression of host responses also occurs.

DOSAGE AND ADMINISTRATION

For topical use only. Shake well before using. In treating ocular inflammatory conditions, one or two drops in the conjunctival sac every hour during the day and every two hours at night is usually adequate to reduce the inflammation. When improvement occurs, the dosage may be reduced to one drop three or four times daily.

AVAILABILITY

Each mL of sterile ophthalmic suspension contains: Sulfacetamide sodium USP 100 mg and prednisolone acetate USP 5 mg.

Non-medicinal Ingredients: Hydroxyethyl cellulose, polysorbate 80, sodium thiosulfate, sodium phosphate (monobasic and dibasic), edetate disodium and benzalkonium chloride 0.025% as preservative.

STORAGE CONDITIONS

Store between 15°C and 30°C. Keep container tightly closed and protected from light.

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

PrODAN-CIDE
Sulfacetamide Sodium and Prednisolone Acetate Ophthalmic Suspension, USP

Read this carefully before you start taking ODAN-CIDE 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-CIDE.

What is ODAN-CIDE used for?

ODAN-CIDE used to treat inflammation in the eye and to treat or prevent bacterial infection. ODAN-CIDE contains an antibacterial ingredient called sulfacetamide sodium, and it should be used exactly as directed by your healthcare professional.

How does ODAN-CIDE work?

ODAN-CIDE contains two medicines that work together to treat your eye:

- Prednisolone acetate is a corticosteroid that reduces inflammation.
- Sulfacetamide sodium is an antibiotic that kills and prevents the growth of bacteria to reduce infections.

What are the ingredients in ODAN-CIDE?

Medicinal ingredients: (each ml contains) Sulfacetamide Sodium and Prednisolone Acetate.

Non-medicinal ingredients: Hydroxyethyl cellulose, polysorbate 80, sodium thiosulfate, sodium phosphate (monobasic and dibasic), edetate disodium and benzalkonium chloride 0.025% as preservative.

ODAN-CIDE comes in the following dosage forms:

- Ophthalmic Suspension, sulfacetamide sodium 10% and prednisolone acetate 0.5%.

Do not use ODAN-CIDE if:

- You are allergic to sulfacetamide sodium, prednisolone acetate or any of the ingredients in this product. You should not use ODAN-CIDE Ophthalmic Suspension if you have a viral or fungal eye infection, tuberculosis of the eye or any previous untreated eye infection.

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

The following may interact with ODAN-CIDE Ophthalmic Suspension:

- Silver solutions.

How to take ODAN-CIDE:

- Misuse or overuse of ODAN-CIDE could lead to the growth of bacteria that will not be killed by sulfacetamide sodium (resistance). This means that ODAN-CIDE or other medicines that contain sulfacetamide sodium may not work for you in the future.
- Do not share your medicine.
- Avoid touching the tip of the tube with your finger or eye to avoid contamination. Put the cap back on after use.
- For topical use only
- To apply:
 - Shake well before using
 - Apply 1 or 2 drops in eyelid (conjunctival sac).

Usual dose: 1 or 2 drops in eyelid every hour daily and every 2 hours at night.
When improvement occurs, the dosage may be reduced to one drop 3 or 4 times daily.

Overdose:

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| If you think you have taken too much ODAN-CIDE, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms. |
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Missed Dose:

If you forget to take ODAN-CIDE, take your dose as soon as you remember. If it is almost time for your next dose of ODAN-CIDE, skip your missed dose and take your next dose at the usual time. Do not apply double the amount to make up for your missed dose.

What are possible side effects from using ODAN-CIDE?

These are not all the possible side effects you may feel when taking ODAN-CIDE. If you experience any side effects not listed here, contact your healthcare professional.

Side effects include:

- Stinging or burning sensation
- Wounds taking longer to heal

| 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 | |
| Visions changes associated with glaucoma (increased eye pressure) and/or cataracts (clouding of the lens of the eye): hazy, blurry or dim vision, eye and head pain, swelling or redness in or around the eye. | | ✓ | |
| Vision changes associated with corneal perforation (thinning or tearing of the front of the eye): worsening of vision or loss of vision. | | | ✓ |
| Stevens-Johnson syndrome (severe skin and mucous membrane reaction): Blisters on your skin and around your eyes, fever, red or purple rash. | | | ✓ |

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 15 and 30 °C. Keep container tightly closed and protected from light.

Keep out of reach and sight of children.

If you want more information about ODAN-CIDE:

- 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); or by contacting the manufacturer, Odan Laboratories Limited at 1-800-387-9342.

This leaflet was prepared by Odan Laboratories Ltd., Montreal, Canada, H9R 2Y6

Last Revised: June 27, 2019