

Prescribing Information

PrODAN-GENTAMICIN

Gentamicin Sulfate Ophthalmic Solution, USP
Gentamicin Sulfate Ophthalmic Ointment, USP

0.3%

Topical antibiotic

Odan Laboratories Ltd.
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Pointe-Claire, Quebec H9Y 2Y6
Control # 227482

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ACTION AND PHARMACOLOGY

Gentamicin is an aminoglycoside antibiotic active against many aerobic gram-negative bacteria and some aerobic gram-positive bacteria. It is inactive against fungi, viruses and most anaerobic bacteria. Although the exact mechanism of action is not known, it appears to inhibit protein synthesis in susceptible organisms by binding to 30S ribosomal subunits.

Gentamicin is usually bactericidal in action. It is active against bacteria commonly found in eye infections: both coagulase positive and negative Staphylococci (including certain strains resistant to penicillin), Group A beta-hemolytic and non-hemolytic streptococci, and *S. pneumoniae*. Gentamicin is also active against gram-negative bacteria, including *Ps. aeruginosa*, indole-positive and negative *Proteus* spp., *K. pneumoniae*, *S. marcescens*, *H. influenzae*, *E. coli*, *N. gonorrhoea*, *Providencia* spp., and *H. vaginocoli*.

In vitro the susceptibility of different species and strains of the same species may show variation. Natural and acquired resistance to gentamicin has occurred in gram-negative and gram-positive bacteria. There is partial resistance between gentamicin and other aminoglycoside antibiotics.

NON-MEDICINAL INGREDIENTS

ODAN-GENTAMICIN Ophthalmic Solution: benzalkonium chloride 0.10% as preservative, sodium chloride, disodium phosphate, monosodium phosphate and purified water.

ODAN-GENTAMICIN Ophthalmic Ointment: methylparaben (as preservative), mineral oil, propylparaben (as preservative) and white petrolatum.

INDICATIONS

ODAN-GENTAMICIN is indicated for the treatment of superficial bacterial infections of the conjunctiva, cornea, eye lids, tear ducts and skin adjacent to the eye. Such infections include conjunctivitis, blepharitis, blepharo-conjunctivitis, keratitis, episcleritis, corneal ulcers, dacryocystitis and infected eye sockets. Also, for prophylaxis to prevent ocular infection after burns, laceration or other injury to the eye, lids or adjacent areas vulnerable to infection (whether caused by physical means or chemical agents) or after removal of foreign bodies and before and after surgery.

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

CONTRAINDICATIONS

ODAN-GENTAMICIN is contraindicated to individuals hypersensitive to gentamicin or other components of the product.

PRECAUTIONS

Clinical studies have shown that organisms previously sensitive to gentamicin have become resistant during therapy. Although this has occurred infrequently, the possibility should nevertheless be considered. There is evidence that cross-resistance between gentamicin and the aminoglycoside antibiotics may occur. However, gentamicin may be active against clinical isolates of bacteria resistant to other aminoglycosides and other aminoglycoside may be active against resistant strains. **Patients should be advised to avoid contaminating the applicator tip during use.**

Pregnancy & Lactation

The safety of gentamicin for use during pregnancy has not been established. Since it is not known whether components of gentamicin Ophthalmic Solution are excreted in human milk, caution should be exercised when administered to a nursing woman.

Use in Children

Safety and effectiveness in children below the age of six years have not been established.

Susceptibility/Resistance

Development of Drug Resistant bacteria

Prescribing ODAN-GENTAMICIN in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant organisms.

Potential for Microbial Overgrowth

Use of topical antibiotics occasionally allows overgrowth of non-susceptible organisms, such as fungi. If this occurs, or if irritation or sensitization develops, use should be discontinued and appropriate therapy instituted.

ADVERSE REACTIONS

ODAN-GENTAMICIN may sting briefly on application. After application, sensitization or allergy is unlikely, however the possibility of such an adverse effect should be kept in mind, and

the patient observed accordingly.

OVERDOSE

Symptoms: A single overdose of gentamicin would not be expected to produce symptoms.

Treatment: Although a single overdose is not expected to require treatment, gentamicin can be removed from the blood by hemodialysis or peritoneal dialysis.

DOSAGE AND ADMINISTRATION

Instill 2 drops into the conjunctival sac or apply a small quantity of the ointment to the affected eye(s) 3 or 4 times daily. Dosage may be increased in severe infections and reduced at the end of treatment. In the infections that may intermittently develop in the immature tear ducts of children (dacryocystitis), hot compresses and massage of the area over the tear duct may be useful adjuncts to ODAN-GENTAMICIN therapy.

AVAILABILITY

ODAN-GENTAMICIN Ophthalmic Solution: (5mg gentamicin sulfate/ml, equivalent to 3 mg gentamicin /mL (0.3%)) is supplied in plastic dropper bottles of 5 ml.

ODAN-GENTAMICIN Ophthalmic Ointment: contains 5 mg/g gentamicin sulfate, equivalent to 3 mg/g gentamicin (0.3%) and supplied in a tube of 3.5 g.

STORAGE

Store between 2 and 30°C.

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

PrODAN-GENTAMICIN
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Read this carefully before you start taking ODAN-GENTAMICIN 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-GENTAMICIN.

What is ODAN-GENTAMICIN used for?

ODAN-GENTAMICIN is used to prevent or treat certain infections in your eye. Antibacterial drugs like ODAN-GENTAMICIN treat only bacterial infections. They do not treat viral infections.

How does Gentamicin work?

ODAN-GENTAMICIN reduces infections by killing bacteria.

What are the ingredients in Gentamicin?

Medicinal ingredients: Gentamicin sulfate.

Non-medicinal ingredients:

ODAN-GENTAMICIN Ophthalmic solution: benzalkonium chloride 0.10% as preservative, sodium chloride, disodium phosphate, monosodium phosphate and purified water.

ODAN-GENTAMICIN Ophthalmic Ointment: methylparaben (as preservative), mineral oil, propylparaben (as preservative) and white petrolatum.

ODAN-GENTAMICIN comes in the following dosage forms:

- Ointment, 0.3%.
- Solution 0.3%

Do not use ODAN-GENTAMICIN if:

- Allergic to Gentamicin or any other ingredients in this product.

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

- Are pregnant or breast-feeding

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

How to take ODAN-GENTAMICIN:

- Although you may feel better early in treatment, ODAN-GENTAMICIN should be used exactly as directed.
- Misuse or overuse of ODAN-GENTAMICIN could lead to the growth of bacteria that will not be killed by ODAN-GENTAMICIN (resistance). This means that ODAN-GENTAMICIN may not work for you in the future.
- Do not share your medicine
- Avoid touching the tip of the applicator with your finger or eye to avoid contamination. Put the cap back on after use.
- Shake the bottle well before using.
- To apply:
 - Pull down your lower eye lid.
 - Instill drops or ointment inside your eyelid (conjunctival sac).
 - Blink to spread the medication.

For children with infected tear ducts (dacryocystitis): Applying a hot compress and massaging the area over the tear duct may help with your child's treatment.

Usual dose:

Solution: Instill 2 drops 3 to 4 times daily.

Dosage may be increased in severe infections and reduced at the end of treatment.

Ointment: Apply a small quantity of the ointment to the affected eye(s) 3 or 4 times daily.

Overdose:

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

Missed Dose:

If you forget to take ODAN-GENTAMICIN, take your dose as soon as you remember. If it is almost time for your next dose of ODAN-GENTAMICIN, 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-GENTAMICIN?

These are not all the possible side effects you may feel when taking ODAN-GENTAMICIN. 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	
Allergic reaction: difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat.			✓

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.

Keep out of reach and sight of children.

If you want more information about ODAN-GENTAMICIN:

- 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>); 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
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