

**PRESCRIBING INFORMATION**  
INCLUDING PATIENT MEDICATION INFORMATION

**Pr ODAN-SPOR**

Neomycin, Polymyxin B Sulfate and Gramicidin Ophthalmic Solution, USP

Neomycin (as Neomycin Sulfate) 1.75 mg / mL  
Polymyxin B Sulfate 10 000 units / mL  
Gramicidin 0.025 mg / mL

**ANTIBIOTIC**

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## **THERAPEUTIC CLASSIFICATION**

ANTIBIOTIC

## **INDICATIONS**

ODAN-SPOR is used for the prophylaxis and treatment of eye infections.

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

## **CONTRAINDICATIONS**

Hypersensitivity to any of the components.

The presence of preexisting nerve deafness is a contraindication to the use of any topical aminoglycoside in circumstances where significant systemic absorption could occur.

## **WARNINGS AND PRECAUTIONS**

The manifestations of sensitization to neomycin are usually itching, reddening and edema of the conjunctiva and eyelid. It may be manifested simply as a failure to heal. During long-term use of neomycin-containing products, periodic examination for such signs is advisable and the patient should be told to discontinue the product if they are observed. These symptoms subside quickly on withdrawing the medication. Neomycin-containing applications should be avoided for the patient thereafter.

### **Susceptibility/Resistance**

#### ***Development of Drug Resistant Bacteria***

Prescribing ODAN-SPOR 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 bacteria.

#### **Potential for Microbial Overgrowth**

The use of ODAN-SPOR may promote the selection of non-susceptible organisms. Should superinfection occur during therapy, appropriate measures should be taken.

Articles in current medical literature indicate an increase in the incidence of allergies to neomycin in patients with stasis ulcers or eczema. The possibility of an allergic reaction to neomycin should be borne in mind.

As with any antibiotic-containing medication, prolonged use may result in the overgrowth of nonsusceptible organisms, including fungi. Should superinfection occur, the preparation should be discontinued and/or appropriate therapy instituted.

Because of the potential hazard of nephrotoxicity and ototoxicity due to neomycin, care should be exercised when treating extensive burns, trophic ulceration and other extensive conditions where absorption of neomycin is possible.

The eye solution should not be given subconjunctivally or intraocularly, nor should it be used for the irrigation of fistulous tracts in or about the eye or its socket.

Treatment should be continued until at least 48 hours after the eye has apparently recovered.

### **ADVERSE EFFECTS**

Topical neomycin occasionally causes skin sensitization, especially when used for prolonged periods of time. Sensitivity to topical neomycin has been reported to occur in 5-15% of patients treated with the drug. Hypersensitivity reactions including contact conjunctivitis, burning, erythema, rash, and urticaria have occurred following topical application of neomycin to patients who are sensitive to the drug or other ingredients in the formulations.

Ototoxicity and nephrotoxicity have also been reported (see **PRECAUTIONS**).

Polymyxin B has a low order of toxicity when applied topically. Allergic hypersensitivity reactions to polymyxin B are rare but have been reported.

## **DOSAGE AND ADMINISTRATION**

The suggested dosage is one or two drops in the affected eye two to four times a day or more frequently as required.

If the infection does not subside within a few days, medical consultation is indicated.

To avoid contaminating the sterile solution, be sure not to touch the infected area with the dropper, when administering the drops.

To prevent the eye drops from being drained from the eye, apply a gentle pressure to the inside corner of the eye with your fingers for one minute.

## **AVAILABILITY**

Each mL contains: polymyxin B sulfate 10 000 units, neomycin sulfate equivalent to 1.75mg neomycin base and gramicidin 0.025mg with ethyl alcohol 0.5%, thimerosal 0.001% (added as a preservative) and the inactive ingredients poloxamer 185, propylene glycol, sodium chloride and water for injection. Sodium hydroxide and/or hydrochloric acid may have been used to adjust pH. Supplied as 10 mL sterile plastic bottles with applicator tip, individually packaged.

## **STORAGE CONDITIONS**

Store between 15°C and 30°C and protect from light.

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PATIENT MEDICATION INFORMATION**

**<sup>Pr</sup>ODAN-SPOR**

**(Neomycin, Polymyxin B Sulfate and Gramicidin Ophthalmic Solution, USP)**

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

**What is ODAN-SPOR used for?**

- ODAN-SPOR is used to prevent and treat infections of the eye.
- Antibacterial drugs like ODAN-SPOR treat only bacterial infections. They do not treat viral infections.

**How does ODAN-SPOR work?**

ODAN-SPOR is an antibiotic that kills and stops the growth of bacteria in the eye.

**What are the ingredients in ODAN-SPOR?**

**Medicinal ingredients:** Contains (per ml): Neomycin 1.75mg, Polymyxin B Sulfate 10 000 units, Gramicidin 0.025mg with ethyl alcohol 0.5% and 0.001% Thimerosal as preservative.

**Non-Medicinal ingredients:** poloxamer 185, propylene glycol, sodium chloride and water for injection. Sodium hydroxide and/or hydrochloric acid (adjust pH).

**ODAN-SPOR comes in the following dosage forms:**

Supplied as 10 mL sterile solution in plastic bottles with applicator tip, individually packaged.

**Do not use ODAN-SPOR if you:**

- are allergic to gramicidin, neomycin or Polymyxin B sulfate
- are allergic to any of the other ingredients in ODAN-SPOR

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

- have skin sores or eczema, a skin condition.

**Other warnings you should know about:**

- Your vision may be blurred for a few minutes after you apply ODAN-SPOR. Do not drive or operate machinery until you can see clearly;
- ODAN-SPOR is for external use only;
- Do not use if solution changes color or becomes cloudy;
- Do not touch tip of bottle to any surface, including your eye, to avoid contamination.

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

**How to take ODAN-SPOR:**

- Although you may feel better early in treatment, ODAN-SPOR should be used exactly as directed;
- Misuse or overuse of ODAN-SPOR could lead to the growth of bacteria that will not be killed by ODAN-SPOR (resistance). This means that ODAN-SPOR may not work for you in the future;
- Do not share your medicine.

**Applying ODAN-SPOR into your eye:**

- Wash hands with soap and water
- Tilt your head back or lie down and look up at 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 eye pouch.
- Slowly release the lower lid.
- To prevent the eye drops from being drained from the eye, apply a gentle pressure to the inside corner of the eye with your fingers for one minute.
- If multiple drops are used, wait three to five minutes between each drop.
- Do not let the bottle touch your eye.
- Contact lenses should not be worn until the infection has resolved.

**Usual dose:**

- The usual dose is one or two drops in the affected eye.
- It is applied two to four times a day.
- Take ODAN-SPOR exactly as directed by your doctor.

**Overdose:**

If you think you have taken too much ODAN-SPOR, 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-SPOR?**

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

Side effects may include:

- itching, redness, or swelling of the eyes or skin;
- burning sensation in the eye;
- feeling of grittiness or having something in the eye;
- eye discharge;

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Kidney problems:</b> abdominal or back pain, changes in your urine, confusion, fatigue, irregular heartbeat, nausea, shortness of breath, swelling, weakness.		✓	
<b>Hearing problems:</b> changes in hearing, dizziness, poor hearing, problems with balance, ringing in the ears, vertigo (spinning sensation).		✓	
<b>Allergic reactions:</b> difficulty breathing, difficulty swallowing, fever, hives, itchy skin, rash, swelling of your tongue or throat.			✓
<b>Eye pain, continued redness or irritation of the eye</b>		✓	

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 15 and 30°C. Protect from light.  
Keep out of reach and sight of children.

### **If you want more information about ODAN-SPOR:**

- 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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