PRESCRIBING INFORMATION
INCLUDING PATIENT MEDICATION INFORMATION

PrODAN-SPOR-HC

Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension, USP

Neomycin (as Neomycin Sulfate) 3.5 mg / mL
Polymyxin B Sulfates 10 000 units / mL
Hydrocortisone 10 mg / mL

ANTIBACTERIAL/ANTI-INFLAMMATORY

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PRESCRIBING INFORMATION

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THERAPEUTIC CLASSIFICATION

ANTIBACTERIAL/ANTI-INFLAMMATORY

ACTION AND CLINICAL PHARMACOLOGY

Corticoids suppress the inflammatory response to a variety of agents and they may delay healing. Since corticoids 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 in a particular case.

The anti-infective components in the combination are included to provide action against specific organisms susceptible to them. Polymyxin B sulfate and neomycin sulfate together are considered active against the following microorganisms: S. aureus, E. coli, H. influenzæ, Klebsiella-Enterobacter species, Neisseria species and P. æruginosa. This product does not provide adequate coverage against S. marcescens and Streptococci, including S. pneumoniæ.

When used topically, polymyxin B and neomycin are rarely irritating and absorption from the intact skin or mucous membrane is insignificant. The incidence of skin sensitization to this combination has been shown to be low on normal skin. Since these antibiotics are seldom used systemically, the patient is spared sensitization to those antibiotics which might later be required systemically.

The relative potency of corticosteroids depends on the molecular structure, concentration, and release from the vehicle.

INDICATIONS AND CLINICAL USE

For the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotics.

ODAN-SPOR-HC contains antibacterial ingredients: polymyxin B and neomycin. To reduce the development of drug-resistant bacteria and maintain the effectiveness of polymyxin B and neomycin, ODAN-SPOR-HC should only be used for the authorized indication and clinical use.

Pediatrics:

Safety of corticosteroids in children aged 2 years or younger has not been established.

CONTRAINDICATIONS

This product is contraindicated in tuberculous, fungal or viral lesions and in those individuals who have shown hypersensitivity to any of its components.

WARNINGS AND PRECAUTIONS

When using neomycin-containing products to control secondary infection in the chronic dermatoses, such as chronic otitis externa or stasis dermatitis, it should be borne in mind that the skin in these conditions is more liable than is normal skin to become sensitized to many substances including neomycin.

The manifestation of sensitization to neomycin is usually a low-grade reddening with swelling, dry scaling and itching. It may be manifested simply as a failure to heal. Periodic examination for such signs is advisable, and the patient should be told to discontinue the product if they are observed. These symptoms regress quickly on withdrawing the medication. Neomycin-containing applications should be avoided for the patient thereafter.

Neomycin may cause cutaneous sensitization. A precise incidence of hypersensitivity reactions (primarily skin rash) due to topical neomycin is not known.

Otic Suspension:

Topical otic preparations containing aminoglycosides have been associated with reports of ototoxicity that may be irreversible. Animal data have shown that aminoglycosides may be absorbed directly across the round window; therefore, there may be an increased risk of ototoxicity in circumstances where there is a perforated tympanic membrane.

The otic suspension should be used with care when the integrity of the tympanic membrane is in question because of the possibility of ototoxicity caused by neomycin. Stinging and burning may occur when this product gains access to the middle ear.

Treatment with the otic suspension should not be continued for longer than 10 days.

Signs and symptoms of exogenous hyperadrenocorticism can occur with the use of topical corticosteroids, including adrenal suppression. Systemic absorption of topically applied steroids will be increased if extensive body surface areas are treated or if occlusive dressings are used. Under these circumstances, suitable precautions should be taken when long-term use is anticipated.

Allergic cross-reactions may occur which could prevent the use of any or all of the following antibiotics for the treatment of future infections: kanamycin, paromomycin, streptomycin, and possibly gentamicin.

Monitoring Laboratory Tests

Systemic effects of excessive levels of hydrocortisone may include a reduction in the number of

circulating eosinophils and a decrease in urinary excretion of 17-hydroxycorticosteroids.

Carcinogenicity
Long-term studies in animals (rats, rabbits, mice) showed no evidence of carcinogenicity attributable to oral administration of corticosteroids.

Susceptibility/Resistance
Development of Drug Resistant Bacteria
Prescribing ODAN-SPOR-HC in the absence of the authorized indications is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

Potential for Microbial Overgrowth
As with any antibiotic preparation, prolonged use may result in the overgrowth of nonsusceptible organisms, including fungi. The possibility of persistent fungal infections of the ear should be considered after prolonged steroid dosing. Appropriate measures should be taken if this occurs. If the infection is not improved after 1 week, cultures and susceptibility tests should be repeated to verify the identity of the organism and to determine whether therapy should be changed.

Special Populations
Pregnant Women: Corticosteroids have been shown to be teratogenic in rabbits when applied topically at concentrations of 0.5% on days 6 to 18 of gestation and in mice when applied topically at a concentration of 15% on days 10 to 13 of gestation. There are no adequate and well-controlled studies in pregnant women. Corticosteroids should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus.

Nursing Women: Hydrocortisone appears in human milk following oral administration of the drug. Since systemic absorption of hydrocortisone may occur when applied topically, caution should be exercised when ODAN-SPOR-HC is used by a nursing woman.

Pediatrics: Safety of corticosteroids in children aged 2 years or younger has not been established. Sufficient absorption of hydrocortisone can occur in infants and children during prolonged use to cause cessation of growth, as well as other systemic signs and symptoms of hyperadrenocorticism.

Use of steroids on infected areas should be supervised with care as anti-inflammatory steroids may encourage spread of infection. If this occurs, steroid therapy should be stopped and appropriate antibacterial drugs used. Generalized dermatological conditions may require systemic corticosteroid therapy.

Information for the Patient

Otic Suspension:
Avoid contaminating the dropper with material from the ear, fingers or other source. This caution is necessary if the sterility of the drops is to be preserved. If sensitization or irritation occurs, discontinue use immediately and contact your physician.

Do not use in the eyes.

If redness, irritation, swelling or pain persists or increases, discontinue use and notify physician.

ADVERSE REACTIONS

Neomycin occasionally causes skin sensitization. In otic use ototoxicity and nephrotoxicity have also been reported (see WARNINGS AND PRECAUTIONS). Exact incidence figures are not available since no denominator of treated patients is available. The reaction occurring most often is allergic sensitization. In one clinical study, using a 20% neomycin patch, neomycin-induced allergic skin reactions occurred in 2 of 2 175 (0.09%) individuals in the general population. In another study, the incidence was found to be approximately 1%. When steroid preparations are used for long periods of time in intertriginous areas or over extensive body areas, with or without occlusive nonpermeable dressings, striae may occur; also there exists the possibility of systemic adverse effects when steroid preparations are used over larger areas or for a long period of time.

The following local adverse reactions have been reported with topical corticosteroids, especially under occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy and miliaria.

Otic Suspension:
Stinging and burning have been reported when this product has gained access to the middle ear.

Secondary Infection: The development of secondary infection has occurred after use of combinations containing steroids and antimicrobials.
Secondary bacterial infection following suppression of host responses also occurs.

OVERDOSAGE

Treatment: Symptomatic.

For management of a suspected drug overdose, contact your regional Poison Control Centre immediately.

DOSAGE AND ADMINISTRATION

Adults: 4 drops of the solution should be instilled into the affected ear 3 or 4 times daily.

Infants and Children: 3 drops are suggested because of the small capacity of the ear canal.

The patient should lie with the affected ear upward and then the drops should be instilled. This position should be maintained for 5 minutes to facilitate penetration of the drops into the ear canal. Repeat, if

necessary for the opposite ear.

If preferred, a cotton wick may be inserted into the canal and then the cotton may be saturated with the solution. This wick should be kept moist by adding further solution every 4 hours. The wick should be replaced at least once every 24 hours.

STORAGE AND STABILITY

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

DOSAGE FORMS, COMPOSITION AND PACKAGING

Each mL of sterile otic suspension contains Neomycin (present as Neomycin Sulfate) 3.5 mg, Polymyxin B Sulfate 10 000 units, Hydrocortisone 10 mg and the following non-medicinal ingredients: Cetyl Alcohol, Polysorbate 80, Propylene Glycol, Purified Water for injection and Thimerosal 0.01% as a preservative. Supplied as a sterile suspension in 10 mL plastic dropper bottles.

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

[Pr]ODAN-SPOR-HC
(Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension USP)

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

What is ODAN-SPOR-HC used for?
ODAN-SPOR-HC is used to treat bacterial infections of the auditory canal (ear).

ODAN-SPOR-HC contains antibacterial ingredients called polymyxin B, and neomycin and it should be used exactly as directed by your healthcare professional.

How does ODAN-SPOR-HC work?
ODAN-SPOR-HC contains two types of medicines:
- Hydrocortisone to reduce inflammation.
- Antimicrobials to kill bacteria and reduce infections.

What are the ingredients in ODAN-SPOR-HC?
Medicinal ingredients: polymyxin B (as sulfate), neomycin (as sulfate) and hydrocortisone. Non-medicinal ingredients are: Cetyl Alcohol, Polysorbate 80, Propylene Glycol, Purified Water for injection and Thimerosal 0.01% as a preservative.

ODAN-SPOR-HC comes in the following dosage forms:
Sterile plastic dropper bottles of 10 mL.

Do not use ODAN-SPOR-HC if you:
- you have tuberculous, fungal or viral lesions.
- are allergic to any of the ingredients in ODAN-SPOR-HC.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ODAN-SPOR-HC. Talk about any health conditions or problems you may have, including if you:
- have a damaged eardrum (tympanic membrane);
- have asthma or allergies;
- are pregnant or planning to become pregnant;
- are breastfeeding or planning to breastfeed.

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-HC:
- You should lie with the affected ear upward and then the drops should be instilled. This position should be maintained for 5 minutes to facilitate penetration of the drops into the ear canal. Repeat, if necessary for the opposite ear.
- If preferred, a cotton wick may be inserted into the canal and then the cotton may be saturated with the solution. This wick should be kept moist by adding further solution every 4 hours. The wick should be replaced at least once every 24 hours.
- Avoid touching the dropper with your ear or fingers to prevent contamination.
- Misuse or overuse of ODAN-SPOR-HC could lead to the growth of bacteria that will not be killed by polymyxin B or neomycin (resistance). This means that ODAN-SPOR-HC or other medicines that contain polymyxin B, or neomycin may not work for you in the future.
- Do not share your medicine.

- Do not use for longer than 10 days.

Usual dose:
Adults: Instill 4 drops into the affected ear 3 or 4 times daily.
Infants and Children: 3 drops are suggested because of the small capacity of the ear canal.

Overdose:

If you think you have taken too much ODAN-SPOR-HC, 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-HC?
These are not all the possible side effects you may feel when taking ODAN-SPOR-HC. If you experience any side effects not listed here, contact your healthcare professional.

The reaction occurring most often is allergic sensitization. The following local adverse reactions have been reported with topical corticosteroids, especially under occlusive dressings:

- dryness;
- sensitivity around hair follicles;
- excessive hair growth;
- acne breakouts;
- bleaching of skin;
- rash around mouth, eyes or nose;
- weakening of the skin;
- secondary infection;
- thinning of the skin;
- heat rash.

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	
Burning, redness, irritation, swelling or pain			✓
Allergic skin reaction			✓

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. Keep container tightly closed.

Keep out of reach and sight of children.

If you want more information about ODAN-SPOR-HC:

- 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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