

PRESCRIBING INFORMATION
INCLUDING PATIENT MEDICATION INFORMATION

^{Pr}JAMP-Nystatin Oral Suspension USP

Nystatin Oral Suspension, USP

100,000 Units / mL

Antifungal

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PRESCRIBING INFORMATION

NAME OF DRUG

PrJAMP-Nystatin Oral Suspension USP

Nystatin Oral Suspension USP

100,000 Units / mL

THERAPEUTIC CLASSIFICATION

Antifungal

CHEMISTRY AND STABILITY

Nystatin is an antifungal antibiotic produced by *Streptomyces noursei*. Each mg of nystatin contains not less than 4400 units of activity. Nystatin deteriorates on exposure to heat, light, moisture, or air.

PHARMACOLOGY

Nystatin exerts its antifungal activity by binding to sterols in the fungal cell membrane. The drug is not active against organisms (e.g., bacteria) that do not contain sterols in their cell membrane. As a result of this binding, the membrane is no longer able to function as a selective barrier, and potassium and other cellular constituents are lost.

Pharmacokinetics:

Nystatin is poorly absorbed from the gastrointestinal tract, and detectable blood concentrations are not obtained after usual doses. Following oral administration, nystatin is excreted almost entirely in feces as unchanged drug. The drug is not absorbed from intact skin or mucous membranes.

SPECTRUM

Nystatin has fungistatic or fungicidal activity against a variety of pathogenic or nonpathogenic yeasts and fungi. In vitro, nystatin concentrations of approximately 3 µm/mL inhibit *Candida albicans* and *C. guilliermondi*. Concentrations of 6.25 µg/mL are required to inhibit *C. krusei* and *Geotrichum lactis*. It is also effective against *Aspergillus spp.*, *Coccidioides immitis*, *Cryptococcus neoformans*, *Histoplasma*, *Capsulatum*, *Blastomyces dermatidis*, and other yeasts and fungi. In general, there is little difference between minimum inhibitory and fungicidal concentrations for a particular organism. Nystatin is not active against bacteria, protozoa, or viruses.

RESISTANCE

Candida rarely becomes resistant in vivo. When resistant strains appear, they frequently are also resistant to other polyene antifungal antibiotics.

INDICATIONS

Prevention and treatment of candidal infections of the oral cavity and esophagus, for intestinal candidiasis and for protection against candidal overgrowth during antimicrobial or corticosteroid therapy.

CONTRAINDICATIONS

Hypersensitivity to nystatin or any components of JAMP-Nystatin Oral Suspension USP. If irritation or sensitization occurs, JAMP-Nystatin Oral Suspension USP should be discontinued.

PRECAUTIONS

Nystatin exhibits no appreciable activity against bacteria, protozoa or viruses.

Fertility:

Studies have not been done to evaluate the effect of nystatin on fertility in either males or females.

Pregnancy:

Studies in humans have not shown that nystatin causes adverse effect on the fetus.

Breast-feeding:

It is not known whether oral nystatin is excreted in breast milk. However, problems in humans have not been documented. The drug should be used with caution in nursing women.

Geriatrics:

No information is available on the relationship of age to the effects of oral nystatin in geriatric patients.

Dental:

Patients with full or partial dentures who have symptomatic oral candidiasis may need to soak their dentures nightly in reconstituted nystatin for oral suspension to eliminate *Candida* species from the dentures. In rare cases when this does not eliminate the fungus, it may be necessary to have new dentures made.

ADVERSE EFFECTS

Large doses have occasionally produced diarrhea, gastrointestinal distress, nausea and vomiting. Tachycardia, bronchospasm, facial swelling, urticarial and non-specific myalgia have been reported rarely.

DOSAGE AND ADMINISTRATION

SHAKE WELL BEFORE USE.

Dosing Considerations

Therapy should generally be continued for at least 48 hours after clinical cure to prevent relapse. When oral nystatin is given concomitantly with an oral antibacterial agent, oral nystatin should be continued at least as long as the antibacterial agent.

Administration

For oral (thrush) and intestinal monilial infections:
Infants and children: 100 000 units 3 to 4 times daily;

Adults: 100,000 units 4 times daily.
Dosage may be increased if necessary.

For treatment of infections of the oral cavity, the medication should be dropped directly on the tongue by means of a calibrated dropper and retained in the mouth for as long as possible before swallowing.

For treatment of intestinal infections, may be dropped directly on the tongue by means of a calibrated dropper or may be mixed with milk, lukewarm formula, or other non-acid vehicles, or incorporated in honey, jelly or peanut butter.

OVERDOSAGE

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

SUPPLIED

Each mL of banana-flavored suspension contains 100 000 units of nystatin and the following non-medicinal ingredients: Anhydrous dibasic sodium phosphate, ammonium glycyrrhizinate, banana flavour, citric acid anhydrous, carboxymethylcellulose sodium, D&C Yellow No. 10, ethyl vanillin, glycerin, maltol, methylparaben, propylene glycol, propylparaben, purified water, sucrose.

JAMP-Nystatin Oral Suspension USP is available in 100 mL and 500 mL high density polyethylene bottles with a polypropylene cap.

STORAGE

Store: 15-30°C.

JAMP-Nystatin Oral Suspension USP should not be used beyond 30 days after opening.

Keep bottle tightly closed. Protect from light.

Keep out of reach and sight of children.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr JAMP-Nystatin Oral Suspension USP

Nystatin Oral Suspension, USP
100,000 Units / mL

Read this carefully before you start taking **JAMP-Nystatin Oral Suspension USP** 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 **JAMP-Nystatin Oral Suspension USP**.

What is JAMP-Nystatin Oral Suspension USP used for?

JAMP-Nystatin Oral Suspension USP is chosen by your doctor to:

- prevent and / or treat fungal infections of the:
 - mouth.
 - esophagus (tube from the mouth to the stomach).
 - intestines.
- most often treat a fungal infection caused by a certain yeast (*Candida*).

How does JAMP-Nystatin Oral Suspension USP work?

JAMP-Nystatin Oral Suspension USP works by killing the yeast or fungus that has caused your symptoms.

What are the ingredients in JAMP-Nystatin Oral Suspension USP?

Medicinal ingredient: 100 000 units of nystatin per mL.

Non-medicinal ingredients: Anhydrous dibasic sodium phosphate, ammonium glycyrrhizinate, banana flavour, citric acid anhydrous, carboxymethylcellulose sodium, D&C Yellow No. 10, ethyl vanillin, glycerin, maltol, methylparaben, propylene glycol, propylparaben, purified water, sucrose.

JAMP-Nystatin Oral Suspension USP comes in the following dosage forms:

Suspension: 100 000 units / mL.

Do not use JAMP-Nystatin Oral Suspension USP if:

- You are allergic to nystatin or any of the ingredients in the product.

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

- Are pregnant, think you may be pregnant, or plan to get pregnant.
- Are breastfeeding or plan 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 JAMP-Nystatin Oral Suspension USP:

This medicine has been prescribed for you or your child and should not be passed on to others. It may harm them even if their symptoms are the same as yours. Always use this medicine exactly as your doctor has told you.

Usual dose:

Your doctor may prescribe for oral (thrush) and intestinal monilial infections:

Infants and children:

100 000 units 3 to 4 times daily.

Adults:

100,000 units 4 times daily.

Dosage may be increased if necessary.

For treatment of infections of the oral cavity, the medication should be dropped directly on the tongue by means of a calibrated dropper and retained in the mouth for as long as possible before swallowing.

For treatment of intestinal infections, may be dropped directly on the tongue by means of a calibrated dropper or may be mixed with milk, lukewarm formula, or other non-acid vehicles, or incorporated in honey, jelly or peanut butter.

Shake the bottle well before use.

If you have a fungal infection of the mouth, tell your doctor if you wear dentures. Special cleaning of the dentures may be required.

Overdose:

If you think you, or a person you are caring for, have taken too much JAMP-Nystatin Oral Suspension USP, contact your healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you miss a dose, take the missed dose as soon as possible, unless it is almost time for your next dose. Skip the missed dose if it is almost time for your next regular dose. Do not take two doses at the same time.

What are possible side effects from using JAMP-Nystatin Oral Suspension USP?

Large doses may produce:

- diarrhea
- nausea
- vomiting

- stomach troubles such as pain and cramps
- tachycardia (abnormally fast heartbeat)
- bronchospasm (sudden narrowing of the airway): difficulty breathing with wheezing or coughing
- facial swelling
- urticarial and non-specific myalgia: muscle pain with hives
- these are not all possible side effects

Contact your doctor if:

- you have a side effect not listed above.
- the side effect(s) become troublesome.
- the side effect(s) interfere with daily activity.

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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store: 15-30°C.

JAMP-Nystatin Oral Suspension USP should not be used beyond 30 days after opening.

Keep bottle tightly closed. Protect from light.

Keep out of reach and sight of children.

If you want more information about JAMP-Nystatin Oral Suspension USP:

- Talk to your healthcare professional.
- Find the full prescribing information that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); or by calling 1-866-399-9091.

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