

**PRESCRIBING INFORMATION**  
**INCLUDING PATIENT MEDICATION INFORMATION**

Pr<sub>pms</sub>-NYSTATIN SUSPENSION

Nystatin Oral Suspension, USP

100,000 Units/mL

**Antifungal**

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Date of Revision:  
January 27, 2017  
Version 1: October 5, 2022

[www.pharmascience.com](http://www.pharmascience.com)

Control no. : 201483

**TABLE OF CONTENTS**

CHEMISTRY AND STABILITY ..... 3

PHARMACOLOGY ..... 3

SPECTRUM..... 4

RESISTANCE..... 4

INDICATIONS ..... 4

CONTRAINDICATIONS ..... 4

PRECAUTIONS ..... 4

ADVERSE EFFECTS..... 5

DOSAGE..... 5

OVERDOSAGE..... 6

SUPPLIED ..... 6

STORAGE..... 6

PATIENT MEDICATION INFORMATION..... 7

## PRESCRIBING INFORMATION

### NAME OF DRUG

Prpms-NYSTATIN SUSPENSION

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 pms-NYSTATIN SUSPENSION. If irritation or sensitization occurs, pms-NYSTATIN SUSPENSION 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.

## DOSAGE

**Newborn:**

For prophylaxis, 100 000 units once daily may be given by dropper directly into the mouth.

**Infants:**

Usual prophylactic and therapeutic dosage is 100 000 units 4 times daily, dropped into the side of the mouth and swallowed. Dosage may be increased if necessary.

**Children and adults:**

Usual therapeutic dose is 100 000 units 4 times daily dropped into the mouth and held or

swished throughout the mouth for as long as possible, then gargled and swallowed.

Shake the bottle well before use.

### **OVERDOSAGE**

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

### **SUPPLIED**

Each mL of yellow, cherry-flavored suspension contains 100 000 units of nystatin and the following non-medicinal ingredients: alcohol, artificial raspberry flavor, artificial wild cherry flavor, citric acid anhydrous (to adjust pH), dibasic potassium phosphate (to adjust pH), D&C yellow n° 10, FD&C red n° 40, glycerine, methylparaben, microcrystalline cellulose and carboxymethyl cellulose sodium, propylene glycol, propylparaben, purified water and sucrose.

pms-NYSTATIN SUSPENSION is available in white plastic unit dose bottles of 5 mL with screw caps, white plastic bottles of 24 mL (with graduated droppers). It is also available in 100 mL and 500 ml graduated amber Pet-G bottles.

### **STORAGE**

Store between 15°C and 30°C. Store in a tight, light- resistant container. Protect from freezing.

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

### PATIENT MEDICATION INFORMATION

#### Pr **pms-NYSTATIN SUSPENSION**

Nystatin Oral Suspension, USP  
100,000 Units/mL

Read this carefully before you start taking **pms-NYSTATIN SUSPENSION** 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 **pms-NYSTATIN SUSPENSION**.

#### **What is pms-NYSTATIN SUSPENSION used for?**

**pms-NYSTATIN SUSPENSION** 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 pms-NYSTATIN SUSPENSION work?**

**pms-NYSTATIN SUSPENSION** works by killing the yeast or fungus that has caused your symptoms.

#### **What are the ingredients in pms-NYSTATIN SUSPENSION?**

Medicinal ingredient: 100 000 units of nystatin per mL.

Non-medicinal ingredients: alcohol, artificial raspberry flavor, artificial wild cherry flavor, citric acid anhydrous (to adjust pH), dibasic potassium phosphate (to adjust pH), D&C yellow n° 10, FD&C red n° 40, glycerine, methylparaben, microcrystalline cellulose and carboxymethyl cellulose sodium, propylene glycol, propylparaben, purified water and sucrose.

#### **pms-NYSTATIN SUSPENSION comes in the following dosage forms:**

**Suspension:** 100 000 units / mL.

#### **Do not use pms-NYSTATIN SUSPENSION 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 pms-NYSTATIN SUSPENSION. 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 breast-feeding 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 pms-NYSTATIN SUSPENSION:**

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:

**Newborn:**

For prevention: Give 1 mL (100 000 units) once per day directly into the mouth using the dropper.

**Infants:**

For prevention and treatment: Give 1 mL (100 000 units) 4 times per day, dropped into the side of the mouth and swallowed.

**Children and adults:**

For treatment: Take 1 mL (100 000 units) 4 times per day dropped into the mouth. Hold or swish the suspension throughout the mouth for as long as possible, then gargle and swallow.

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 have taken too much pms-NYSTATIN SUSPENSION, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms. Take this leaflet or your medication with you so that the hospital or poison control centre will know what you have taken.

**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 pms-NYSTATIN SUSPENSION?

Large doses may produce:

- diarrhea.
- nausea.
- vomiting.
- stomach troubles such as pain and cramps.
- 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 help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

#### 3 ways to report:

Online at [MedEffect](#);

- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 1908C  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

*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°C and 30°C. Store in a tight, light-resistant container. Protect from freezing.

Keep out of reach and sight of children.

**If you want more information about pms-NYSTATIN SUSPENSION:**

- Talk to your healthcare professional.
- Find the full prescribing information that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#); or by calling 1-888-550-6060.

This leaflet was prepared by:

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Last Revised: January 27, 2017