

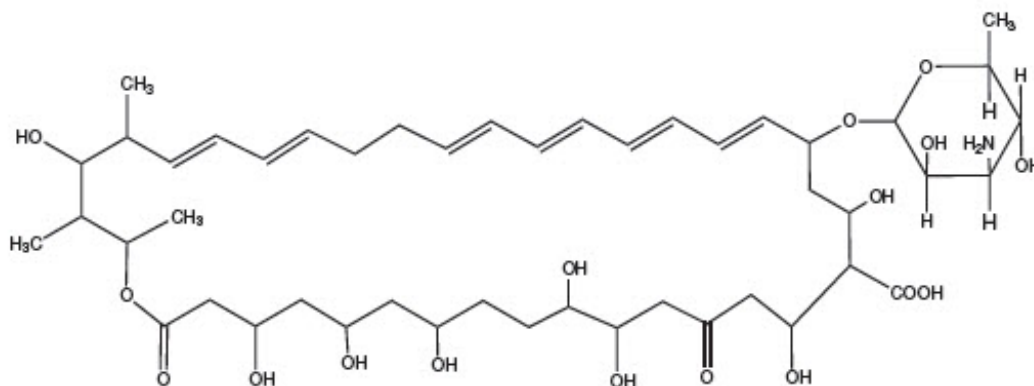
**NYSTATIN- nystatin suspension**  
**Taro Pharmaceuticals U.S.A., Inc.**

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**Nystatin**  
**Oral Suspension,**  
**USP**

**Rx Only**

**DESCRIPTION**

Nystatin is an antimycotic polyene antibiotic obtained from *Streptomyces noursei*. Structural formula:



Nystatin Oral Suspension, for oral administration, is cherry/mint flavored, containing 100,000 USP Nystatin Units per mL. Inactive ingredients: alcohol ( $\leq 1\%$  v/v), benzaldehyde, edetate calcium disodium, flavors, glycerin, magnesium aluminum silicate, methylparaben, propylparaben, purified water, saccharin sodium, sodium citrate, sucrose (49.8% w/v), xanthan gum.

**CLINICAL PHARMACOLOGY**

**Pharmacokinetics**

Gastrointestinal absorption of nystatin is insignificant. Most orally administered nystatin is passed unchanged in the stool. In patients with renal insufficiency receiving oral therapy with conventional dosage forms, significant plasma concentrations of nystatin may occasionally occur.

**Microbiology**

Nystatin is both fungistatic and fungicidal *in vitro* against a wide variety of yeasts and yeast-like fungi. *Candida albicans* demonstrates no significant resistance to nystatin *in vitro* on repeated subculture in increasing levels of nystatin; other *Candida* species become quite resistant. Generally, resistance does not develop *in vivo*. Nystatin acts by binding to sterols in the cell membrane of susceptible *Candida* species with a resultant change in membrane permeability allowing leakage of intracellular components. Nystatin exhibits no appreciable activity against bacteria, protozoa, or viruses.

**INDICATIONS AND USAGE**

Nystatin Oral Suspension is indicated for the treatment of candidiasis in the oral cavity.

## **CONTRAINDICATIONS**

The preparation is contraindicated in patients with a history of hypersensitivity to any of its components.

## **PRECAUTIONS**

### **General**

This medication is not to be used for the treatment of systemic mycoses. Discontinue treatment if sensitization or irritation is reported during use.

### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

No long-term animal studies have been performed to evaluate carcinogenic potential. There also have been no studies to determine mutagenicity or whether this medication affects fertility in males or females.

### **Pregnancy**

#### **Teratogenic Effects Category C**

Animal reproduction studies have not been conducted with nystatin oral suspension. It is also not known whether nystatin oral suspension can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nystatin oral suspension should be given to a pregnant woman only if clearly needed.

### **Nursing Mothers**

It is not known whether nystatin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when nystatin is administered to a nursing woman.

### **Pediatric Use**

See **DOSAGE AND ADMINISTRATION**.

## **ADVERSE REACTIONS**

Nystatin is well tolerated even with prolonged therapy. Oral irritation and sensitization have been reported. (See **PRECAUTIONS: General**).

*Gastrointestinal:* Diarrhea (including one case of bloody diarrhea), nausea, vomiting, gastrointestinal upset/disturbances.

*Dermatologic:* Rash, including urticaria has been reported rarely. Stevens-Johnson syndrome has been reported very rarely.

*Other:* Tachycardia, bronchospasm, facial swelling, and non-specific myalgia have also been rarely reported.

## **OVERDOSAGE**

Oral doses of nystatin in excess of five million units daily have caused nausea and gastrointestinal upset. There have been no reports of serious toxic effects of superinfections (See **CLINICAL PHARMACOLOGY, Pharmacokinetics**).

## **DOSAGE AND ADMINISTRATION**

## **INFANTS**

2 mL (200,000 units) four times daily (in infants and young children, use dropper to place one-half of dose in each side of mouth and avoid feeding for 5 to 10 minutes).

**NOTE:** Limited clinical studies in premature and low birth weight infants indicate that 1 mL four times daily is effective.

## **CHILDREN AND ADULTS**

4 to 6 mL (400,000 to 600,000 units) four times daily (one-half of dose in each side of mouth). The preparation should be retained in the mouth as long as possible before swallowing.

Continue treatment for at least 48 hours after perioral symptoms have disappeared and cultures demonstrate eradication of *Candida albicans*.

## **HOW SUPPLIED**

Nystatin Oral Suspension, USP, 100,000 USP Nystatin U/mL, is available as a cherry-mint flavored, light creamy yellow, ready-to-use suspension in:

2 fl oz (60 mL) bottles with 0.5 mL, 1 mL, 1.5 mL, 2 mL calibrated dropper NDC 51672-4117-4 1 Pint (473 mL) bottles NDC 51672-4117-9 1 Gallon (3785 mL) bottles (For repackaging only) NDC 51672-4117-0

## **SHAKE WELL BEFORE USING**

### **Storage**

**Store at 20° to 25°C (68° to 77°F)** [see USP Controlled Room Temperature]. Protect from freezing.

**PHARMACIST:** Dispense in a tight, light-resistant container as defined in USP.

Manufactured by:

Taro Pharmaceutical Industries Ltd.

Haifa Bay, Israel 2624761

Distributed by:

**Taro Pharmaceuticals U.S.A., Inc.**

Hawthorne, N.Y. 10532

Revised: May 2019

70564-0519-2

## **PRINCIPAL DISPLAY PANEL - 60 mL Bottle Label**

NDC 51672-4117-4

2 fl oz  
(60 mL)

Nystatin

Oral Suspension USP,


100,000 units/mL

SHAKE WELL BEFORE USING

CHERRY/MINT FLAVORED

TARO

Rx only



NDC 51672-4117-4

# Nystatin

## Oral Suspension USP,

**100,000 units/mL**

SHAKE WELL BEFORE USING  
CHERRY/MINT FLAVORED

2 fl oz  
(60 mL)

**Each mL contains:** 100,000 units of Nystatin in a vehicle containing alcohol (≤1% v/v), sucrose (49.8% w/v) with methylparaben and propylparaben as preservatives. **Usual dosage:** For Infants: 2 mL (200,000 units) four times daily (in infants and young children, use dropper to place one-half of dose in each side of mouth and avoid feeding for 5 to 10 minutes). **Usual dosage:** For Children and Adults: See package insert for full prescribing information.


**WARNINGS:** **Keep this and all medications out of the reach of children.** In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

**Store at 20° to 25°C (68° to 77°F)** [see USP Controlled Room Temperature]. **Protect from Freezing.**

Dispense in a tight, light-resistant container as defined in the USP. **Before dispensing, replace cap with safety cap dropper.**

For lot number and expiry date see bottle or carton.  
Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel 2624761  
Dist. by: **Taro Pharmaceuticals U.S.A., Inc.**, Hawthorne, NY 10532

70539-0419-1



**Rx only**

## NYSTATIN

nystatin suspension

### Product Information

|                                |                         |                           |                |
|--------------------------------|-------------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:51672-4117 |
| <b>Route of Administration</b> | ORAL                    |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength              |
|---|-------------------|-----------------------|
| Nystatin (UNII: BDF1O1C72E) (Nystatin - UNII: BDF1O1C72E) | Nystatin          | 100000 [USPU] in 1 mL |

### Inactive Ingredients

| Ingredient Name                                     | Strength |
|---|----------|
| alcohol (UNII: 3K9958V90M)                          |          |
| benzaldehyde (UNII: TA269SD04T)                     |          |
| edetate calcium disodium (UNII: 25IH6R4SGF)         |          |
| glycerin (UNII: PDC6A3C0OX)                         |          |
| magnesium aluminum silicate (UNII: 6M3P64V0NC)      |          |
| methylparaben (UNII: A2I8C7HI9T)                    |          |
| propylparaben (UNII: Z8IX2SC1OH)                    |          |
| water (UNII: 059QF0K00R)                            |          |
| saccharin sodium (UNII: SB8ZUX40TY)                 |          |
| sodium citrate, unspecified form (UNII: 1Q73Q2JULR) |          |
| sucrose (UNII: C151H8M554)                          |          |
| xanthan gum (UNII: TTV12P4NEE)                      |          |

### Product Characteristics

|              |                              |              |  |
|--------------|------------------------------|--------------|--|
| <b>Color</b> | YELLOW (light creamy yellow) | <b>Score</b> |  |
| <b>Shape</b> |                              | <b>Size</b>  |  |

| <b>Flavor</b>                | CHERRY (Cherry-mint flavored)            |   | <b>Imprint Code</b>  |                    |
|------------------------------|--|---|----------------------|--------------------|
| <b>Contains</b>              |  |   |                      |                    |
| <b>Packaging</b>             |  |   |                      |                    |
| #                            | Item Code                                | Package Description   | Marketing Start Date | Marketing End Date |
| 1                            | NDC:51672-4117-4                         | 1 in 1 CARTON   | 02/29/1988           |                    |
| 1                            |  | 60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product |                      |                    |
| 2                            | NDC:51672-4117-9                         | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product         | 02/29/1988           |                    |
| 3                            | NDC:51672-4117-0                         | 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product        | 02/29/1988           |                    |
| <b>Marketing Information</b> |  |   |                      |                    |
| Marketing Category           | Application Number or Monograph Citation | Marketing Start Date  | Marketing End Date   |                    |
| ANDA                         | ANDA062876                               | 02/29/1988  |                      |                    |

**Labeler** - Taro Pharmaceuticals U.S.A., Inc. (145186370)

### Establishment

| Name                                | Address | ID/FEI    | Business Operations     |
|-------------------------------------|---------|-----------|-------------------------|
| Taro Pharmaceutical Industries Ltd. |         | 600072078 | MANUFACTURE(51672-4117) |

Revised: 7/2019

Taro Pharmaceuticals U.S.A., Inc.