**nystatin (Nystatin) suspension**
[Actavis Mid Atlantic, LLC]

# DESCRIPTION

Nystatin is an antimycotic polyene antibiotic obtained from Streptomyces noursei.

Structural formula:

[IC]C47H75NO17 MW 926.13

[/IC]

Nystatin Oral Suspension for oral administration contains 100,000 USP Nystatin Units per mL.

Inactive ingredients: Alcohol (≤ 1% v/v), D&C Yellow #10, dibasic sodium phosphate, edetate calcium disodium, flavors, glycerin, magnesium aluminum silicate, methylparaben (0.18%) and propylparaben (0.03%) added as preservatives, purified water, sucrose (50% w/v).

# 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 nonspecific 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 or superinfections (see CLINICAL PHARMACOLOGY, Pharmacokinetics).

# DOSAGE AND ADMINISTRATION

Infants: 2 mL (approximately ½ teaspoon) (200,000 units) four times daily. Place one-half of dose, 1 mL (approximately ¼ teaspoon), 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: 4-6 mL (approximately 1 teaspoon) (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 is available as a yellow, cherry-flavored, pleasant-tasting, ready-to-use suspension containing 100,000 USP Nystatin Units per mL in 60 mL bottles (supplied with a calibrated dropper), 8 oz (237 mL) bottles (supplied with dose cup) and one pint (473 mL) bottles.

SHAKE WELL BEFORE USING.

Store at controlled room temperature 59°-86°F (15°-30°C). Avoid freezing.

Dispense in a tight, light-resistant container as defined in the USP.

Manufactured by
Actavis Mid Atlantic LLC
7205 Windsor Blvd.
Baltimore, MD 21244 USA

FORM 1320

Rev.9/06

VC2903

Nystatin (Nystatin)

PRODUCT INFO

| | | | |
|---|---|---|---|
| Product Code | 0472-1320 | Dosage Form | SUSPENSION |
| Route Of Administration | ORAL | DEA Schedule | |

INGREDIENTS

| Name (Active Moiety) | Type | Strength |
|---|---|---|
| **Nystatin** (Nystatin) | Active | 100000 UNITS In 1 MILLILITER |
| **alcohol** | Inactive | |
| **d&c yellow#10** | Inactive | |
| **dibasic sodium phosphate** | Inactive | |
| **edetate calcium disodium** | Inactive | |
| **flavors** | Inactive | |
| **glycerin** | Inactive | |
| **magnesium aluminum silicate** | Inactive | |
| **methylparaben** | Inactive | |
| **propylparaben** | Inactive | |
| **water** | Inactive | |
| **surcrose** | Inactive | |

IMPRINT INFORMATION

| | | |
|---|---|---|
| Characteristic Appearance | Characteristic | Appearance |
| Color | Score | |
| Shape | Symbol | |
| Imprint Code | Coating | |
| Size | | |

PACKAGING

| # | NDC | Package Description | Multilevel Packaging |
|---|---|---|---|
| **1** | 0472-1320-02 | 60 MILLILITER In 1 BOTTLE, DROPPER | None |
| **2** | 0472-1320-98 | 237 MILLILITER In 1 BOTTLE | None |
| **3** | 0472-1320-16 | 473 MILLILITER In 1 BOTTLE | None |

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