

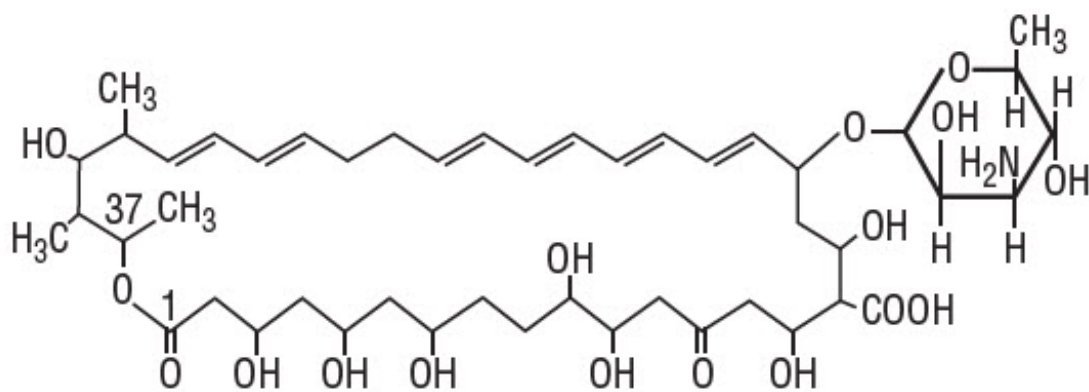
NYSTATIN- nystatin suspension
Bryant Ranch Prepack

NYSTATIN ORAL
SUSPENSION, USP
(100,000 units per mL)

Rx only

DESCRIPTION

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



C₄₇H₇₅NO₁₇

MW = 926.13

Nystatin Oral Suspension, for oral administration, is cherry/mint flavored, containing 100,000 USP Nystatin Units per mL. Inactive ingredients: disodium edetate, sodium benzoate, sodium hexametaphosphate, dibasic sodium phosphate heptahydrate, monobasic sodium phosphate monohydrate, glycerin, methyl paraben, propyl paraben, sucrose, cherry flavor and peppermint oil.

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

4–6 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 Units per mL, is available as a cherry-mint flavored, yellow, ready-to-use suspension.

1 Pint (473 mL) bottles (NDC: 63629-2492-1)

SHAKE WELL BEFORE USE

Storage

Store at 20° - 25°C (68° - 77°F); excursions permitted between 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature]. AVOID FREEZING.

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

Repackaged/Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504

Manufactured for:

Nivagen Pharmaceuticals, Inc.
Sacramento, CA 95827
Toll Free Number: 1-877-977-0687

Rev: 06/2020

Nystatin Oral Suspension, #473



GTIN
Lot
Exp
SN

Each mL contains: 100,000 Units Nystatin USP in a vehicle containing sucrose, disodium edetate, sodium benzoate, sodium hexametaphosphate, dibasic sodium phosphate heptahydrate, monobasic sodium phosphate monohydrate, glycerin, cherry flavor, peppermint oil with methylparaben and propylparaben as preservatives.

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

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

NDC 63629-2492-1

Nystatin Oral Suspension,
USP

100,000 units/ mL



Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

Rx only
473 mL
Manufactured by:
Nivagen Pharmaceuticals,
Inc.

6362924921



NYSTATIN

nystatin suspension

Product Information

| | | | |
|-------------------------|-------------------------|--------------------|-------------------------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:63629-2492(NDC:75834-235) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------------|
| NYSTATIN (UNII: BDF1O1C72E) (NYSTATIN - UNII:BDF1O1C72E) | NYSTATIN | 100000 [USP'U] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| HEXASODIUM HEXAMETAPHOSPHATE (UNII: N40N91DW96) | |
| SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70WT22SF4B) | |
| SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| SUCROSE (UNII: C151H8M554) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |

| Product Characteristics | | | | |
|-------------------------|--|---|----------------------|--------------------|
| Color | YELLOW | | Score | |
| Shape | | | Size | |
| Flavor | CHERRY (MINT) | | Imprint Code | |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:63629-2492-1 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/14/2020 | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| ANDA | ANDA062832 | | 08/14/2020 | |
| | | | | |

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

| Establishment | | | |
|----------------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| Bryant Ranch Prepack | | 171714327 | REPACK(63629-2492) , RELABEL(63629-2492) |