DISCLAIMER

All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akorn's Customer Service department at 800.932.5676.
Each mL contains 100,000 units of nystatin in a vehicle containing 50% w/v sucrose with the following inactive ingredients: alcohol (less than 1% v/v), carboxymethylcellulose sodium, cherry flavor, citric acid, glycerin, peppermint flavor, purified water, and sodium citrate. Citric acid and/or sodium hydroxide may be used to adjust pH (5.3-7.5).

Preservatives: Methylparaben 0.12%, Propylparaben 0.03%

**USUAL DOSAGE:**
- **Infants:** 2 mL (200,000 units) four times daily (1 mL in each side of mouth).
- **Pediatric Patients and Adults:** 4 to 6 mL (400,000 to 600,000 units) four times daily (one-half dose in each side of mouth).

Read enclosed insert for complete product information.


**WARNING - NOT FOR INJECTION**
Pediatric Use

See DOSAGE AND ADMINISTRATION section for pediatric dosage recommendations.

Adverse Reactions

To report SUSPECTED ADVERSE REACTIONS, contact Hi-Tech Pharmacal Co., Inc. at 1-800-262-9010 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Gastrointestinal symptoms including diarrhea, gastrointestinal distress, nausea, vomiting and burning of the mouth have been reported. Hypersensitivity reactions including rash, pruritus, and anaphylactoid reaction have also been reported.

Overdose

Oral doses of nystatin in excess of five million units daily have caused nausea and gastrointestinal upset.

Infants: 2 mL (200,000 units) four times daily (1 mL in each side of mouth).

Pediatric patients and adults: 4 to 6 mL (400,000 to 600,000 units) four times daily (one-half of dose in each side of mouth).

NEONATES, indicate that 1 mL (100,000 units) four times daily is effective.

Local treatment should be continued at least 48 hours after perioral symptoms have disappeared and/or cultures returned to normal. It is recommended that the drug be retained in the mouth as long as possible before swallowing.

How Supplied

Nystatin Oral Suspension USP, 100,000 units per mL, is available as a yellow, milky, ready-to-use suspension with a cherry-mint flavor in the following sizes:

60 mL bottles (with child-resistant calibrated dropper)

A 2 mL calibrated dropper with 1 mL calibrations is provided with the 60 mL container.


Information for the Patient

Manufactured by:

Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701

Each mL contains 100,000 units of nystatin in a vehicle containing 50% w/v sucrose with the following inactive ingredients: alcohol (less than 1% v/v), carboxymethylcellulose sodium, cherry flavor, citric acid, glycerin, peppermint flavor, purified water, and sodium citrate.

Citic acid and/or sodium hydroxide may be used to adjust pH (5.3-7.5).

Preservatives: Methylparaben 0.12%, Propylparaben 0.03%

Usual Dosage

Infants: 2 mL (200,000 units) four times daily (1 mL in each side of mouth).

Pediatric Patients and Adults: 4 to 6 mL (400,000 to 600,000 units) four times daily (one-half dose in each side of mouth).

Read enclosed insert for complete product information.


Hi-TECH PHARMACAL CO., INC.

Amityville, NY 11701

Rev. 587:00 5/11

Each mL contains 100,000 units of nystatin in a vehicle containing 50% w/v sucrose with the following inactive ingredients: alcohol (less than 1% v/v), carboxymethylcellulose sodium, cherry flavor, citric acid, glycerin, peppermint flavor, purified water, and sodium citrate.

Citic acid and/or sodium hydroxide may be used to adjust pH (5.3-7.5).

Preservatives: Methylparaben 0.12%, Propylparaben 0.03%

Usual Dosage

Infants: 2 mL (200,000 units) four times daily (1 mL in each side of mouth).

Pediatric Patients and Adults: 4 to 6 mL (400,000 to 600,000 units) four times daily (one-half dose in each side of mouth).

Read enclosed insert for complete product information.


Hi-TECH PHARMACAL CO., INC.

Amityville, NY 11701

Rev. 587:00 5/11

Each mL contains 100,000 units of nystatin in a vehicle containing 50% w/v sucrose with the following inactive ingredients: alcohol (less than 1% v/v), carboxymethylcellulose sodium, cherry flavor, citric acid, glycerin, peppermint flavor, purified water, and sodium citrate.

Citic acid and/or sodium hydroxide may be used to adjust pH (5.3-7.5).

Preservatives: Methylparaben 0.12%, Propylparaben 0.03%

Usual Dosage

Infants: 2 mL (200,000 units) four times daily (1 mL in each side of mouth).

Pediatric Patients and Adults: 4 to 6 mL (400,000 to 600,000 units) four times daily (one-half dose in each side of mouth).

Read enclosed insert for complete product information.


Hi-TECH PHARMACAL CO., INC.

Amityville, NY 11701

Rev. 587:00 5/11

Each mL contains 100,000 units of nystatin in a vehicle containing 50% w/v sucrose with the following inactive ingredients: alcohol (less than 1% v/v), carboxymethylcellulose sodium, cherry flavor, citric acid, glycerin, peppermint flavor, purified water, and sodium citrate.

Citic acid and/or sodium hydroxide may be used to adjust pH (5.3-7.5).

Preservatives: Methylparaben 0.12%, Propylparaben 0.03%

Usual Dosage

Infants: 2 mL (200,000 units) four times daily (1 mL in each side of mouth).

Pediatric Patients and Adults: 4 to 6 mL (400,000 to 600,000 units) four times daily (one-half dose in each side of mouth).

Read enclosed insert for complete product information.


Hi-TECH PHARMACAL CO., INC.

Amityville, NY 11701

Rev. 587:00 5/11

Each mL contains 100,000 units of nystatin in a vehicle containing 50% w/v sucrose with the following inactive ingredients: alcohol (less than 1% v/v), carboxymethylcellulose sodium, cherry flavor, citric acid, glycerin, peppermint flavor, purified water, and sodium citrate.

Citic acid and/or sodium hydroxide may be used to adjust pH (5.3-7.5).

Preservatives: Methylparaben 0.12%, Propylparaben 0.03%

Usual Dosage

Infants: 2 mL (200,000 units) four times daily (1 mL in each side of mouth).

Pediatric Patients and Adults: 4 to 6 mL (400,000 to 600,000 units) four times daily (one-half dose in each side of mouth).

Read enclosed insert for complete product information.


Hi-TECH PHARMACAL CO., INC.

Amityville, NY 11701

Rev. 587:00 5/11