

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use NATACYN safely and effectively. See full prescribing information for NATACYN.

**NATACYN® (natamycin ophthalmic suspension) 5%,
for topical ophthalmic use**
Initial U.S. Approval: 1978

INDICATIONS AND USAGE

NATACYN is a polyene antimicrobial indicated for the treatment of fungal blepharitis, conjunctivitis, and keratitis caused by susceptible organisms including *Fusarium solani* keratitis. (1)

DOSAGE AND ADMINISTRATION

- Initial dosage in the treatment of fungal keratitis is one drop instilled in the conjunctival sac at an hourly or two-hourly intervals. The frequency of application can usually be reduced to one drop 6 to 8 times daily after the first 3 to 4 days. Therapy should generally be continued for 14 to 21 days or until there is resolution of active fungal keratitis. In many cases, it may be helpful to reduce the dosage gradually at 4 to 7 day intervals to assure that the replicating organism has been eliminated. Failure of improvement of keratitis following 7 to 10 days of administration of the drug suggests that the infection may be caused by a microorganism not susceptible to natamycin. (2.1)
- Less frequent initial dosage (4 to 6 daily applications) may be sufficient in fungal blepharitis and conjunctivitis (2.1)

DOSAGE FORMS AND STRENGTHS

Ophthalmic suspension: 5%. (3)

CONTRAINDICATIONS

NATACYN is contraindicated in patients with hypersensitivity to any of its components. (4)

WARNINGS AND PRECAUTIONS

- Epithelial Ulceration:** Adherence of the suspension to areas of epithelial ulceration occurs regularly. (5.1)
- Retention of the Suspension in the Fornices:** frequently occurs. (5.2)

ADVERSE REACTIONS

The most common adverse reactions are allergic reactions, change in vision, chest pain, corneal opacity, dyspnea, eye discomfort, eye edema, eye hyperemia, eye irritation, eye pain, foreign body sensation, paresthesia, and tearing. (6.2)

To report SUSPECTED ADVERSE REACTIONS, contact Harrow at 844-446-6979 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 11/2025

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* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

NATACYN is indicated for the treatment of fungal blepharitis, conjunctivitis, and keratitis caused by susceptible organisms including *Fusarium solani* keratitis.

As in other forms of suppurative keratitis, initial and sustained therapy of fungal keratitis should be determined by the clinical diagnosis, laboratory diagnosis by smear and culture of corneal scrapings and drug response. Whenever possible, the *in vitro* activity of natamycin against the responsible fungus should be determined. The effectiveness of natamycin as a single agent in fungal endophthalmitis has not been established.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage and Administration

Initial dosage for the treatment of fungal keratitis is one drop instilled in the conjunctival sac at an hourly or two-hourly intervals. The frequency of application can usually be reduced to one drop 6 to 8 times daily after the first 3 to 4 days. Therapy should generally be continued for 14 to 21 days or until there is resolution of active fungal keratitis. In many cases, it may be helpful to reduce the dosage gradually at 4 to 7-day intervals to assure that the replicating organism has been eliminated.

Failure of improvement of keratitis following 7 to 10 days of administration of the drug suggests that the infection may be caused by a microorganism not susceptible to natamycin. Continuation of therapy should be based on clinical re-evaluation and additional laboratory studies.

Less frequent initial dosage of 4 to 6 daily applications may be sufficient in fungal blepharitis and conjunctivitis.

Shake well before using.

3 DOSAGE FORMS AND STRENGTHS

NATACYN contains natamycin 5% (50 mg/mL).

4 CONTRAINDICATIONS

NATACYN is contraindicated in patients with hypersensitivity to any of its components.

5 WARNINGS AND PRECAUTIONS

5.1 Adherence to Epithelial Ulceration

Adherence of the suspension to areas of epithelial ulceration occurs regularly.

5.2 Retention in Fornices

Retention of the suspension in the fornices frequently occurs.

5.3 Risk of Contamination

Do not touch the dropper tip of the bottle to the eye, eyelids, or to any surface, as this may contaminate the contents. Use only if the container is undamaged.

5.4 Avoidance of Contact Lens Use

Patients should be advised not to wear contact lenses if they have signs and symptoms of fungal blepharitis, conjunctivitis, and keratitis.

6 ADVERSE REACTIONS

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of NATACYN. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Allergic reaction, change in vision, chest pain, corneal opacity, dyspnea, eye discomfort, eye edema, eye hyperemia, eye irritation, eye pain, foreign body sensation, paresthesia, and tearing.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

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

8.2 Lactation

Risk Summary

It is not known whether natamycin is excreted in human milk. Caution should be exercised when NATACYN is administered to a nursing patient.

8.4 Pediatric Use

The safety and effectiveness of NATACYN have not been established in pediatric patients.

8.5 Geriatric Use

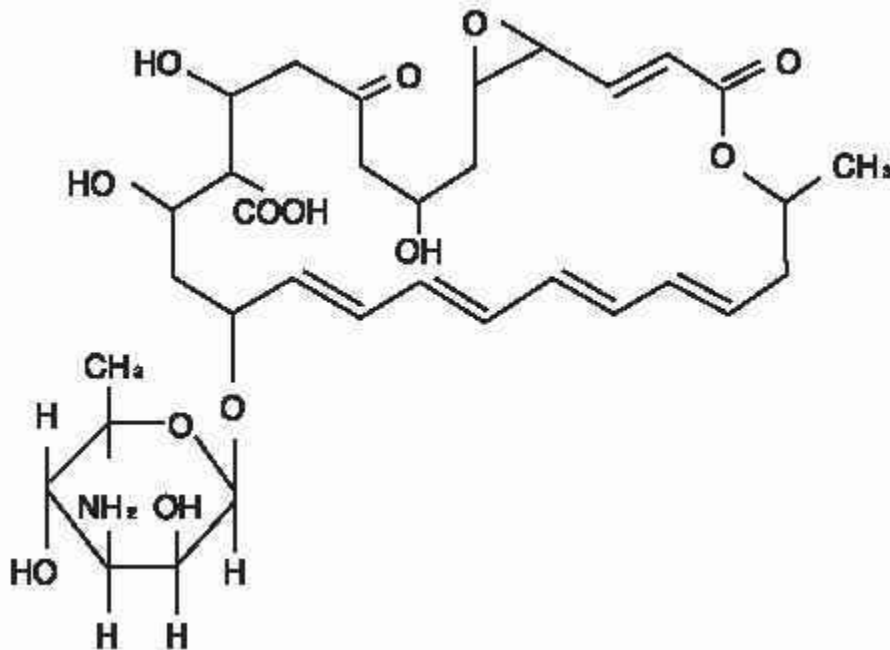
No overall differences in safety or effectiveness have been observed between elderly and younger patients.

11 DESCRIPTION

NATACYN (natamycin ophthalmic suspension) 5% is a sterile, antifungal drug for topical ophthalmic use with a pH range of 5.0 – 7.5. It contains the active pharmaceutical ingredient, natamycin.

The chemical name of natamycin is stereoisomer of 22-[(3-amino-3,6-dideoxy- β -D-mannopyranosyl)oxy]-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.1.05,7] octacos-8,14,16,18,20-pentaene-25-carboxylic acid. Its chemical formula is $C_{33}H_{47}NO_{13}$ and has a molecular weight of 665.73 g/mol.

Natamycin is also known as Pimaricin and is represented by the chemical structure:



Each mL of NATACYN contains:

Active Ingredient: natamycin 5% (50 mg)

Preservative: benzalkonium chloride 0.02%

Inactive Ingredients: sodium hydroxide and/or hydrochloric acid (neutralized to adjust the pH), purified water.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Natamycin is a tetraene polyene antibiotic derived from *Streptomyces natalensis*. It possesses *in vitro* activity against a variety of yeast and filamentous fungi, including *Candida*, *Aspergillus*, *Cephalosporium*, *Fusarium* and *Penicillium*. The mechanism of action appears to be through binding of the molecule to the sterol moiety of the fungal cell membrane. The polyenesterol complex alters the permeability of the membrane to produce depletion of essential cellular constituents. Although the activity against fungi is dose-related, natamycin is predominantly fungicidal. Natamycin is not effective *in vitro* against gram-positive or gram-negative bacteria. Topical administration appears to

produce effective concentrations of natamycin within the corneal stroma but not in intraocular fluid. Systemic absorption should not be expected following topical administration of NATACYN. As with other polyene antibiotics, absorption from the gastrointestinal tract is very poor. Studies in rabbits receiving topical natamycin revealed no measurable compound in the aqueous humor or sera, but the sensitivity of the measurement was no greater than 2 mg/mL.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential, mutagenic potential, or impairment of fertility of natamycin.

16 HOW SUPPLIED/STORAGE AND HANDLING

NATACYN (natamycin ophthalmic suspension) 5% is supplied in an amber glass bottle with a black phenolic closure. A flint glass dropper with a red plastic closure and a black rubber bulb are packaged separately in a clear plastic blister with Tyvek backing.

NDC 82667-012-05 – 15 mL in 15 mL bottle

STORAGE: Store between 2°C to 24°C (36°F to 75°F). *Do not freeze.* Avoid exposure to light and excessive heat.

Shake well before using.

17 PATIENT COUNSELING INFORMATION

Risk of Contamination

Instruct patients to not touch the dropper tip to the eye, eyelids, or to any surface, as this may contaminate the contents. Advise patients to use the product only if the container is undamaged [see [Warnings and Precautions \(5.3\)](#)].

Contact Lens Wear

Advise patients to not wear contact lenses if they have signs and symptoms of fungal blepharitis, conjunctivitis, and keratitis. [see [Warnings and Precautions \(5.4\)](#)].

Manufactured for:
Harrow Eye, LLC
102 Woodmont Blvd. Suite 610
Nashville, TN 37205
USA