

NatasolTM

Eye Drops

(Natamycin Ophthalmic Suspension IP)

COMPOSITION:

Natamycin IP	5.0% w/v
Benzalkonium Chloride Solution IP	0.02% v/v
(as preservative)	
Water for Injections IP	q.s.

Pharmacological 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.

Pharmacokinetics:

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 natamycin ophthalmic suspension 5%. 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.

Indications:

Natamycin ophthalmic suspension 5% 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.

Dosage and administration:

Shake well before use.

The preferred initial dosage in fungal keratitis is one drop of natamycin ophthalmic suspension, 5% instilled in the conjunctival sac at 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. Less frequent initial dosage (4 to 6 daily applications) may be sufficient in fungal blepharitis and conjunctivitis.

Contraindications

Natamycin ophthalmic suspension, 5% is contraindicated in individuals with a history of hypersensitivity to any of its components.

Warnings

For topical ophthalmic use only. Not for injection

Precautions:

General: If irritation persists or increases, discontinue the use and consult the Physician.

Do not touch dropper tip to any surface, as this may contaminate the suspension.

Failure of improvement of keratitis following 7-10 days of administration of 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. Should suspicion of drug toxicity occur, the drug should be discontinued.

Drug interactions:

No specific drug interactions have been studied with topical natamycin suspension

Pregnancy:

Pregnancy category c

It is not known whether natamycin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Natamycin ophthalmic suspension 5% should be given to a pregnant woman only if clearly needed.

Storage and handling instructions:

Keep in a cool place

Use the suspension within one month after opening the container.

Do not touch the tip of the container to any surface. Replace cap after using. Protect from light.

KEEP OUT OF REACH OF CHILDREN

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

SHAKE WELL BEFORE USE

Presentation:

Natasol is a sterile ophthalmic suspension supplied in opaque plastic dropper bottle with a cap, Containing 5 ml of the suspension.

Directions for use:



Turn the tamper proof cap anti-clockwise to break the seal.



Remove the cap, dispense drops with gentle pressure.

Replace the cap immediately after every use.

Manufactured in INDIA by :

Senses Pharmaceuticals Pvt. Ltd.,

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TM: Trademark for Registration

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