For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

(Natamycin Ophthalmic Suspension USP)

NATASOL™

Eye Drops

For the use of Registered Medical Practitioner only

COMPOSITION:

Natamycin USP ..... 5.0% w/v
Benzalkonium Chloride Solution USP ..... 0.02% v/v
(as preservative)
Water for Injection USP ..... 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:
Store between 15°C - 30°C.
PROTECT FROM LIGHT.

Shelf life
24 months from the date of Manufacture

KEEPOUT OF REACH OF CHILDREN
NOT FOR INJECTION
FOR EXTERNAL USE ONLY
SHAKE WELL BEFORE USE

Presentation:
5 mL of off white to creamy coloured suspension filled in 5mL Sterile Gamma-irradiated white opaque LDPE bottle sealed with Sterile Gamma-irradiated natural transparent LDPE open nozzle and Sterile Gamma-irradiated white HDPE tamp safe cap in printed carton along with leaflet.

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.,
No.77, 3rd Road, Bommasandra Industrial Area,
Bommasandra 4th Phase, Bengaluru - 560 099.
Email: info@sensespharma.com

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