



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

Natamycin Ophthalmic Suspension USP

NATAMET*

PXP11387

Composition:

Each ml of **NATAMET** contains Natamycin USP 50 mg in sterile aqueous base.

Clinical Pharmacology:

Natamycin is a sterile, antifungal drug for topical ophthalmic administration. It is a tetraene polyene antibiotic derived from *Streptomyces natalensis*.

Mechanism of Action:

Natamycin possesses in vitro activity against a variety of yeast and filamentous fungi, including *Candida*, *Aspergillus*, *Cephalosporium*, *Fusarium* and *Penicillium*. Its 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. Natamycin does not have effect in vitro against gram-positive or gram-negative bacteria. Natamycin is predominantly fungicidal.

Topical administration appears to produce effective concentrations of natamycin within the corneal stroma but not in intraocular fluid.

Pharmacokinetics:

Following topical administration of natamycin, systemic absorption should not be expected. 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 humour or sera.

Indications:

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

Contraindications:

Natamycin is contraindicated in individuals with history of hypersensitivity to the drug and any of its ingredients.

Warnings and Precautions:

Natamycin ophthalmic suspension is for topical eye use only—NOT FOR INJECTION. Continuation of therapy should be based on clinical re-evaluation and additional laboratory studies.

Adherence of the suspension to areas of epithelial ulceration occurs regularly. Therefore, patient should be monitored at least twice weekly. Should suspicion of drug toxicity occur, medication should be discontinued.

Safety & effectiveness in children have not been established.

Pregnancy & Lactation

It is not known whether natamycin can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, natamycin should be given to a pregnant woman only if clearly needed. Also, it is not known whether natamycin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when natamycin is administered to a nursing woman.

Drug Interactions:

No drug interactions have been reported.

Side effects:

Adverse events due to natamycin ophthalmic suspension reported are contact dermatitis, conjunctival chemosis and hyperemia of allergic nature. Systemic absorption may result in nephrotoxicity.

Dosage and Administration:

SHAKE WELL BEFORE USE: The recommended initial dosage in fungal keratitis is one drop of **Natamet** instilled in the conjunctival area 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.

Storage:

Store in a cool dark place.

Information for Patients:

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

Presentation:

Natamet is available as 50 mg/ml in 5 ml vials with sterile plastic dropper.

For further details, please write to:

sun pharmaceutical ind. ltd.

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Andheri(E), Mumbai 400 059, INDIA.

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