



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetic industries.

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TECHNICAL DATA SHEET

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79463-NYSTATIN

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1 Identification of the substance or preparation.

Name: Nystatin

Bulk code: 79463

1.2 Synonyms.

Botanical name: Nystatinum; Fungicidin.

2. DESCRIPTION

Appearance: Powder.

Colour: Yellow or slightly brownish.

Odour: Characteristic.

Hygroscopic.

Loses its activity in the presence of light, air and heat.

3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula: $C_{47}H_{75}NO_{17}$

CAS No.: 1400-61-9

Molecular weight: 926.1 g/mol

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis bulletin.

Solubility: Very poorly soluble in water; practically insoluble in alcohol, chloroform, acetone and ether; slightly soluble in methanol and easily soluble in dimethylformamide.

5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

Nystatin is an antifungal substance produced by certain strains of *Streptomyces noursei*. It is made up predominantly of tetraenes, the major component of which is nystatin A1. Its activity must not be less than 4400 IU per milligram, calculated with respect to dried substance.

It is an antifungal antibiotic with a fungistatic action, pertaining to the group of polyene macrolides, which acts by altering the permeability of the fungus membrane, forming ion



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channels in it. It has a broad antifungal spectrum, including against dermatophytes and yeasts, as is the case with Candida, although its action on dermatophytes is only moderate.

6. DOSAGE.

Topical use:

- Prophylaxis and treatment of chronic cutaneous and mucocutaneous candidiasis, in the form of ointments, creams, gels or powders, at doses of 100,000 IU/g applied 2–4 times daily.

Orally:

- Treatment of intestinal and oropharyngeal candidiasis in the form of lozenges, capsules, tablets and suspensions, in doses of 500,000 or 1,000,000 IU, three or four times a day.
- Infants and children are dosed with 100,000 IU or more, four times a day.
- Oral infections: in the form of gels and suspensions, in doses of 100,000 IU, every 6 hours; these preparations should be kept as long as possible on the affected area, avoiding the ingestion of food and drink for at least one hour after use. After the symptoms resolve, it is recommended to continue treatment for at least 48 hours.

Vaginally:

- Vulvovaginal candidiasis therapy, in dosages of 100,000–200,000 IU daily, for 14 days, in the form of vaginal pessaries, tablets and creams.

7. REMARKS.

STORAGE:

Store at room temperature ($25\pm 2^{\circ}\text{C}$) in a cool, dry place, away from light, in a tightly closed container.

8. BIBLIOGRAPHY.

Monografías Farmacéuticas. COF Alicante, 1998.

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).