



AURA LIFECARE PVT. LTD.

Product: NYSTATIN VAGINAL TABLETS USP

MODULE: 1

1.4 Product Information

1.4.1 Summary of Products Characteristics (SmPC)

1. Name of the medicinal product

NYSTATIN VAGINAL TABLETS USP

2. Qualitative and quantitative composition

Each uncoated tablet contains:

Nystatin USP..... 100.000 IU

Excipients q.s.

3. Pharmaceutical form

Solid oral

Light yellow coloured bullet shaped tablets plain on both the sides

4. Clinical particulars

4. Clinical Particulars

4.1 Indication

Nystatin is indicated for the treatment of cutaneous, mucocutaneous, oral, intestinal and vulvovaginal infections caused by *Candida albicans*.

4.2 Posology and Administration

three times daily. Treatment should generally be continued for at least 48 hours after clinical cure to prevent a relapse.

4.3 Contraindication

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special Warning & precautions for use

This medication is not to be used for the treatment of systemic mycoses. Discontinue treatment if sensitization or irritation is reported during use.

4.5 Interaction with other medicinal products and other forms of interaction

Not known.

4.6 Fertility, Pregnancy and lactation

Not Known.

4.7 Effects on ability to drive and use machines

This medication has no or negligible influence on the ability to drive or use machinery.

4.8 Undesirable effects

Nystatin is well tolerated by all age groups even with prolonged administration. Large oral doses have occasionally produced diarrhea, gastrointestinal distress, nausea and vomiting

Module 1: ADMINISTRATIVE INFORMATION



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4.9 Overdose

Not known.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Nystatin is an antifungal antibiotic, produced by a strain of *Streptomyces noursei*, active against yeasts and yeast like fungi, including *Candida albicans*. The antifungal activity is probably due to the binding of sterols in the cell membrane of the fungus with a resultant change in membrane permeability allowing leakage of intracellular components. Nystatin has no appreciable activity against bacteria.

5.2 Pharmacokinetic properties

Nystatin is absorbed very sparingly following oral administration when given in the recommended doses. The minimal absorption from oral dosage forms may however, be sufficient to provoke an allergic reaction in hypersensitive patients. No detectable blood levels are obtained following topical or vaginal applications.

6. Shelf Life

36 months

7. Special precaution for Storage

Store in a dry place, below 30°C. Protect from light.

8. Nature and contents of container

1 x 14 tablets in a carton along with insert.

9. Manufacturer

Aura Lifecare Pvt. Ltd.

S. No. 254/ 1411, Jarod-Savli Road, P.O. Karachiya-391 520,

Tal. Savli, Dist. Vadodara