

Prescribing information (Summary of product characteristics)

1. Name of the medicinal product

Labstatin Vaginal Tablets

2. Qualitative and quantitative composition

Each tablets contains: Nystatin BP 100,000 I.U and excipients provided in section 6.1

3. Pharmaceutical form

Tablets

Pale yellow, biconvex, capsule shaped tablets, plain on both sides, packed in 15's with applicator and contained in a unit box with literature insert.

4. Clinical Particulars

4.1 Therapeutic Indications

Prophylaxis and treatment of diseases, caused by *oidium albicans*: treatment of candidiasis of the mucous membranes (vagina). With prophylactic mean to prevent the development of candidiasis during protracted antibiotic therapy, as well as in case of cachexia and in patients with immune deficiency.

4.2 Dosage and administration

Pessaries

Route of administration: Vagina

Adults including the elderly

1 or 2 pessaries should be inserted high into the vagina for 14 consecutive nights or longer, regardless of any intervening menstrual period

Children

Not recommended

How to use Labstatin applicator

1. Pull back the applicator plunger about 2.5 centimeters (1 inch). Inset the tablet into the cup at the end of the hollow tube (applicator)
2. Lie on your back with your knees drawn up. Insert the applicator into your vagina as far as it will comfortably go. Do not try to force it to go further.
3. Be sure the applicator is in the correct position in your vagina before you insert the plunger.
4. Then, push the plunger to place the tablet in your vagina
5. Remove the applicator. Wash with mild soap and warm water. Rinse thoroughly and dry

4.3 Contraindications

There are no contraindications to use nystatin, except hypersensitivity to any of the ingredients

4.4 Special Warnings and Precautions for Use

N/A

4.5 Interaction with other medicinal products and other forms of Interaction

Other drugs may interact with nystatin, including prescription and over-the-counter medicines, **vitamins**, and **herbal products**.

4.6 Pregnancy and Lactation

In pregnancy care should be taken when using the applicator provided to prevent the possibility of mechanical trauma and injury to the uterus.

4.7 Effects on Ability to Drive and Use Machines

None unknown

4.8 Undesirable Effects

Nystatin is generally well tolerated. In rare cases allergic reactions may be observed, which fade away with the discontinuation of Nystatin treatment, nausea, vomiting, diarrhea or abdominal pains may occur with hypersensitivity patients and high-dose nystatin treatment. Should any hypersensitivity reaction occur or other infections develop in the course of the treatment, the administration of the drug has to be discontinued and appropriate therapy should be instituted instead.

4.9 Overdose and treatment

Take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not take extra medicine to make up the missed dose

5. Pharmacological properties

5.1 Pharmacodynamic properties

ATC Code: G01AA01

Nystatin is a polyene antibiotic, amphoteric tetraen, containing mycosamin. Nystatin acts on the cytoplasmic membrane of the bacterial cell, inhibiting its permeability. Nystatin exerts its effect by interaction with cell walls and cell membranes. Sterols present in the cell membrane are necessary for this effect.

Nystatin has both fungistatic and fungicidal effects. Generally, the preparation exerts fungistatic effect, but in high concentrations fungicidal effect is also observed. Nystatin possessed high activity against fungi, yeasts and oidium albicans. Its 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 biding of sterols in the cell membrane of the fungus with the resultant change in membrane of the fungus with a resultant change in membrane permeability allowing leakage of intracellular components. Nystatin in vitro amounts to 1.56-6.2µg/ml. Nystatin exerts amebicidal effects as well. However, it does not possess activity against bacteria, protozoae, trichomonades or viruses.

.2 Pharmacokinetic properties

Nystatin is insignificantly absorbed from the gastrointestinal tract and is eliminated unchanged with the faeces. It is absorbed very sparingly following oral administration when given in recommended doses. The minimal absorption from oral dosage forms may however, be sufficient to provoke an allergic reaction in hypersensitive patients

In renal insufficiency patients, nystatin may attain significant plasma concentrations. No detectable blood levels are obtained following vaginal applications.

5.3 Preclinical safety data

There is no pre-clinical data of relevance to a prescriber, which is additional to that already included in other sections of the SPC.

6. Pharmaceutical Particulars

6.1 List ofExcipients

- Dummy Lactose Granules
- Sodium Starch Glycolate
- Sodium bicarbonate
- Purified talc
- Magnesium stearate

6.2 Incompatibilities

None.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store in a dry place, below 30°C

Protect from light

Keep all medicines out of reach of children

6.5 Nature and Contents of Container

Pale yellow, biconvex, capsule shaped tablets, plain on both sides, packed in15's (3 x 5's) with applicator and contained in a unit box

6.6 Special precaution for disposal and other handling

No special requirements.

7 Marketing Authorization Holder and Manufacturing Site Addresses Marketing

Authorization Holder:

Company Name: LABORATORY & ALLIED LTD

Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa road, P.O. Box 42875
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8 Marketing Authorization Number:

KENYA: Registration No. H96/375

9 Date of first Registration/ Renewal of the Registration:

KENYA: Date of registration: 03/10/1996

10 Date of revision of the text:

November 2023.