

Prescribing information (Summary of product characteristics)

1. NAME OF THE MEDICINAL PRODUCT

Labstatin Vaginal Tablets.

Strength:

Nystatin 100,000 I.U

Pharmaceutical Form:

Tablets for vagina use.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablets contains:

Nystatin BP100,000 I.U.

Full list of excipients provided in section 6.1

3. PHARMACEUTICAL FORM

Tablets for vagina use.

Pale yellow, biconvex, capsule shaped tablets, plain on both sides. Packed in PVC/ ALU blisters of 3 x 5'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 candidiases 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:

Not Applicable.

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 Fertility, 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 Known.

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.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>

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:

Pharmacotherapeutic Group: Genito Urinary System and Sex Hormones, Gynecological Antiinfectives and Antiseptics.

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.

5.2 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 of excipients:

- Dummy Lactose Granules
- Sodium Starch Glycolate
- Sodium Bicarbonate
- Magnesium Stearate
- Purified Talc

6.2 Incompatibilities:

None Known.

6.3 Shelf Life:

36 Months from the manufacture date.

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 in ALU/PVC blisters of 3 x 5's with applicator and contained in a unit box with literature insert.

6.6 Special precaution for disposal and other handling:

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6.7 Distribution Category:

Prescription Only Medicine (POM).

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES:

Marketing Authorization Holder:

Company Name: Laboratory & Allied Limited.

Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa road, P.O. Box 42875 GPO 00100, Nairobi-Kenya.

Country : Kenya

Telephone : +254 20 8040306

Telefax : +254 20 8040309

E-Mail : info@laballied.com.

Manufacturing Site Address:

Company Name: Laboratory & Allied Limited.

Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa road, P.O. Box 42875 GPO 00100, Nairobi-Kenya.

Country : Kenya

Telephone : +254 20 8040306

Telefax : +254 20 8040309

E-Mail : info@laballied.com

8. MARKETING AUTHORIZATION NUMBER

Kenya: Registration No.: H96/375.

9. DATE OF FIRST <REGISTRATION> / RENEWAL OF THE <REGISTRATION>

Date of first authorization: 03/10/1996.

Date of latest renewal: Retained Annually.

10. DATE OF REVISION OF THE TEXT

October, 2025. , 12th August 2026