

PATIENT INFORMATION LEAFLET
(NEOVAG) NYSTATIN VAGINAL INSERTS USP 100000 IU

[Nystatin USP]

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

1. What nystatin vaginal inserts is and what it is used for
2. Before you use nystatin vaginal inserts
3. How to use nystatin vaginal inserts
4. Possible side effects
5. How to store nystatin vaginal inserts
6. Further information

1. WHAT NYSTATIN VAGINAL INSERTS IS AND WHAT IT IS USED FOR

It is a polyene ionophore antifungal used to treat cutaneous, mucocutaneous, and gastrointestinal mycotic infections, particularly those caused by *Candida species*. It has both fungistatic and fungicidal effects. Nystatin exhibits no appreciable activity against bacteria, protozoa, trichomonads or viruses. It is effective for the local treatment of *vulvovaginal candidiasis (moniliasis)*. The diagnosis should be confirmed, prior to therapy, by potassium hydroxide (KOH) smears and/or cultures, other pathogens commonly associated with *vulvovaginitis (Trichomonas and Haemophilus vaginalis)* do not respond to nystatin and should be ruled out by appropriate laboratory methods.

2. BEFORE YOU USE NYSTATIN VAGINAL INSERTS

Do not use it if you are allergic to **nystatin** or any of the other ingredients of this medicine. If you are not sure, talk to your physician, pharmacist or nurse before having nystatin vaginal inserts.

Take special care with nystatin vaginal inserts:

Warnings and Precautions: Talk to your physician before taking nystatin vaginal inserts. If you have now or have had in the past. **General:** Discontinue treatment if sensitization or irritation is reported during use. **Information for Patients:** The patient should be warned against interruption or stoppage of medication even during menstruation and even though symptomatic relief may occur within a few days. The patient should be advised that adjunctive measures such as therapeutic douches are unnecessary and sometimes inadvisable, but cleansing douches may be used by non-pregnant women, if desired, for esthetic purposes. Pregnant women take advice physician if clearly needed to use. It is unlikely that nystatin vaginal inserts. It may harm your developing baby.

Patient take precautions: Some intravaginal preparations of nystatin may damage latex contraceptives and additional contraceptive precautions may be necessary during treatment.

Laboratory Tests: If there is a lack of response to nystatin vaginal inserts, appropriate microbiological studies should be repeated to confirm the diagnosis and rule out other pathogens before instituting another course of antimycotic therapy.

Pediatric: Safety and effectiveness of nystatin vaginal tablet in pediatric population is not established. **Using other medicines:** Not Known. **Using nystatin vaginal inserts with food and drink:** None. **Before taking any medicine for advice consult to direction of physician.** **Pregnancy and breast-feeding: Pregnancy:** It is also not known whether nystatin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nystatin should be given to a pregnant woman only if clearly needed. Pregnant women must not use the applicator provided with nystatin vaginal inserts. **Lactation:** It is unlikely that nystatin is excreted in human milk in sufficient amounts to affect your baby. However, it is recommended that caution should be exercised when nystatin is administered to a nursing woman.

Driving and using machines: Not Known.

3. HOW TO USE NYSTATIN VAGINAL INSERTS

Always take your dose of nystatin vaginal inserts exactly as qualified person, like a physician or a nurse has told you, you should check with your physician, health care provider or pharmacist if you are not sure. Do not change your usual dose without talking to your physician.

How nystatin vaginal inserts will be given to you: Dosage must be individualized on the basis of the disease and the response of the patient. **Method of Administration:** Intra-Vaginal use only. Not For Oral Use. **Adults:** The usual dosage is one nystatin vaginal tablet daily at bedtimes for two weeks or longer as given follow the doctor's instructions. The nystatin vaginal inserts should be deposited high in the vagina by means of the applicator. **Directions for Insertion:** nystatin vaginal inserts should be used with applicator and follow below given instruction for use. 1. Remove one vaginal tablet from the strip pack. 2. Pull out the plunger till it stops & Place one tablet into the applicator. 3. Carefully insert the applicator containing tablet as deeply as possible into the vagina. This is best achieved when lying on the back. 4. Carefully push the plunger till it stops. This pushes the tablet into the vagina. Withdraw the applicator from the vagina. 5. After use, pull out the plunger completely from the applicator and wash both components in warm water. Clean & dry them.

Note: Pregnant women should strictly follow the doctor's instructions. **Elderly:** Refer to adult dosing. **If you more nystatin vaginal inserts than you should:** Oral doses of nystatin in excess of five million units daily have caused nausea and gastrointestinal upset. Since the absorption of nystatin from the gastro-intestinal tract is negligible, over-dosage causes no systemic toxicity.

If you forget to nystatin vaginal inserts: It is important to take nystatin vaginal inserts as prescribed by your physician. If you miss a dose. Do not take a double dose to make up for the forgotten dose. **If you stop using nystatin vaginal inserts:** It can be dangerous to have your treatment with nystatin vaginal inserts stopped abruptly. If you have any further questions on the use of this product, ask your physician, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist. Nystatin is virtually nontoxic and non-sensitizing and is well tolerated by all age groups, even on prolonged administration. Rarely, irritation or sensitization may occur.

5. HOW TO STORE NYSTATIN VAGINAL INSERTS

Keep this medicine out of the sight and reach of children. Store below 30°C. Protect from light & moisture. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any

unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

It contain active substances as Nystatin USP. Excipients: Lactose (Lactose Monohydrate), Colloidal Anhydrous Silica (Aerosil), Maize Starch, Povidone (P.V.P.K-30), Magnesium Stearate, Purified Talc, Colloidal Anhydrous Silica (Aerosil), Sodium Starch Glycolate (Type-A), Microcrystalline Cellulose (PH 102), Purified Water. Pack size: Off white coloured, almond shaped, uncoated tablet, plain on both sides. 10 tablets are strip packed. Such 10 strip is packed in a Printed Carton with Packing Insert.

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