PACKAGE LEAFLET: Information for the patient

NYSTAGO

Oral suspension – 100,000 I.U./ ml

(Nystatin)

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness 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 doctor or pharmacist.

In this leaflet:

1. WHAT NYSTAGO IS AND WHAT IT IS USED FOR

NystaGo contains the active substance nystatin. Nystatin, a polyene antifungal antibiotic, is a mixture of substances produced by the growth of certain strains of *Streptomyces noursei* or through other methods. Mostly it consists of nystatin A_1. Nystatin is active against a wide range of yeasts or fungus similar to yeasts, including *Candida albicans*.

It is indicated in the prevention and treatment of oral cavity, esophagus and gastrointestinal tract infections caused by fungus of *Candida* species.

It also provides an effective prophylaxis against oral candidiasis in infants whose mothers suffer from vaginal candidiasis.

Your doctor may have given NystaGo for another purpose. Ask your doctor if you want to know why you have been given NystaGo.

2. BEFORE YOU TAKE NYSTAGO

Do not take NystaGo if you are hypersensitive to nystatin or to any of the excipients of the oral suspension.

Take special care with NystaGo

Ask your doctor before you get NystaGo!

NystaGo suspension contains sucrose, therefore it should not be given to individuals who suffer from intolerance to disaccharides. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking NystaGo.

People holding a prosthesis should be careful with its cleaning during treatment with this medicine.

NystaGo should be used only if necessary during pregnancy and only after consultation with your doctor or pharmacist.

It is not used for the treatment of systemic mycoses.

Discontinue treatment if you notice any sign of sensitivity or irritation when taking the medicine.

Taking other medicines

Simultaneous treatment with other medicines may affect or be affected by NystaGo. Please contact your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription. Do not forget to inform your doctor about NystaGo treatment if you are given any other medicine during treatment. No interactions with other drugs have been noticed.

Pregnancy

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant. No reproduction studies have been conducted in animals with nystatin suspension. It is not known whether it can cause fetal harm or can affect reproductivity if administered to a pregnant woman.

NystaGo should be used during pregnancy only if the doctor considers it very necessary. Always consult your doctor before using NystaGo during pregnancy.

Category C.

Breastfeeding

It is not known if nystatin is excreted in breast milk. Since many drugs are excreted in breast milk, caution should be taken when administering NystaGo during breastfeeding.

Driving and using machines

No effects during driving and using machines have been noticed.

Important information about some of the excipients of NystaGo

NystaGo contains:

- methyl hydroxybenzoate and propyl hydroxybenzoate, which may cause allergic reactions (possibly delayed);
- sucrose; if you have been told by your doctor that you or your child has an intolerance to some sugars, contact your doctor before taking/giving this medicinal product.

3. HOW TO TAKE NYSTAGO

Always take NystaGo according to the advice of a doctor. If you are not sure, contact your doctor or pharmacist. If you feel that NystaGo effects are very strong or too weak, talk to your doctor or pharmacist.

Shake well the bottle before use.

Method of administration

Take with the pipette as much suspension as needed, till the mark line (0,5 ml or 1 ml), while in the case of the spray pump, administer the suspension directly in the mouth, and then swallow it.

Spray pump: 1 spray is equal to 0,5 ml, 2 sprays are equal to 1 ml.

Take NystaGo after the meals and disperse it inside the mouth for approximately 1 minute, in order to achieve a good moistening of the whole oral cavity.

Dosage is given as below:

For the treatment of ulcerations (wounds) as a result of the prosthesis and oral infections in adults caused by *Candida albicans,* 1 ml of suspension, is administered 4 times a day.

In patients with immunodeficiency, higher doses of 5 ml suspension should be administered, 4 times a day. The suspension should remain in contact with the infected areas as long as possible.

For the treatment of intestinal or esophageal candidiasis should be administered 5 ml of suspension orally, 4 times a day.

A daily dose for prophylaxis of 1,000,000 I.U. inhibits the overproduction of *Candida albicans* in patients treated with broad-spectrum antibiotics.

Children: In the oral and intestinal candidiasis in infants and children should be administered 1 ml of suspension, 4 times a day.

For the prophylaxis of neonatal intestinal candidiasis the suggested dose is 1 ml, once a day.

Elderly: No specific recommendations or special care for this group age.

The maximum therapeutic effect is achieved when the suspension is kept in the mouth for as long as possible before swallowing.

The administration must be continued for other 48 hours after the completion of the treatment to avoid the recurrence.

If you have taken more NystaGo

If you have taken more NystaGo than the amount that you should, or if the children have taken this medicine by mistake, please contact your doctor, the hospital, or call the emergency to get an opinion on the risk and advice on the actions that must be taken.

Daily doses higher than 5,000,000 I.U. of nystatin suspension showed diarrhea and gastrointestinal disturbances. Due to the low or almost negligible absorption of nystatin in the gastrointestinal tract, overdose or accidental ingestion do not cause systemic toxicity.

If you forget to take NystaGo

If you forget a dose (or more doses), take the next dose when it is time to take it as usual.

Do not take a double dose (or higher) to make up for the forgotten dose (doses).

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, NystaGo can cause side effects, although not everybody gets them. NystaGo is well tolerated at recommended doses.

Tell your doctor about side effects that may occur.

Rarely sensitisation or oral irritation is manifested. Occasionally, cases with nausea during therapy with nystatin have been reported. Large doses of oral nystatin cause diarrhea, gastrointestinal disturbances, nausea and vomiting.

In rare cases rash, urticaria, angioedema (swelling of the lips or tongue) and facial edema have also been reported.

Very rarely Stevens-Johnson syndrome has been reported.

If any of the side effects worsens, or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

If you experience any of the above side effects, treatment with NystaGo should be discontinued and you should consult with your doctor or pharmacist.

5. HOW TO STORE NYSTAGO

Keep out of the reach and sight of children.

Do not use NystaGo after the expiry date which is stated on the package.

Store below 25°C!

Store in the original packaging to protect it from light.

6. OTHER INFORMATION

What NystaGo oral suspension contains

The **active substance** is nystatin.

1 ml of suspension contains 100,000 I.U.nystatin.

The **excipients** are: propylene glycol, sucrose, saccharin sodium, citric acid monohydrate,

polyvinylpyrrolidone 90, polysorbate 80, sodium citrate, methyl parahydroxybenzoate (nipagin), propyl parahydroxybenzoate (nipasol), ethanol 96%, essence citri and purified water.

Content of the pack:

- Carton box with one glass bottle of 30 ml suspension, accompanied by a graduated pipette.
- Carton box with one glass bottle of 48 ml suspension, with a spray pump.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,
St. "Skënder Vila",
Tirana, Albania.
Tel.: +355 4 23 89 602

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