

PACKAGE LEAFLET: INFORMATION FOR THE USER

NYSTATIN

100.000 IU/1g ointment

NYSTATIN

• *This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

• *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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

What is in this leaflet?

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

1. WHAT NYSTATIN IS AND WHAT IT IS USED FOR

Nystatin belongs to a group of so-called anti-fungal medicines.

Nystatin ointment is intended for the treatment of fungal infections of the skin and mucous membranes caused by *Candida albicans* (Monilia) and other types of *Candida*.

2. BEFORE YOU USE NYSTATIN

Warn the doctor if you are taking other medicines, you have a chronic disease, a disorder of metabolism, hypersensitivity to medicine or have had an allergic reaction to some of them.

Nystatin ointment should not be used:

- If you are hypersensitive to any component of this medicine.

When you are taking Nystatin ointment, take special care:

If during treatment with Nystatin you experience hypersensitivity reactions, you should immediately suspend the therapy.

Nystatin ointment should not be used in ophthalmology (to treat infections of the eye).

Use of other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those that can be purchased without a prescription.

There are no data that there are interactions between nystatin and other medicines.

Pregnancy and breastfeeding

Before you start taking any medicine, consult your doctor or pharmacist.

There are no special restrictions on the use of this medicine during pregnancy and breastfeeding.

Driving and using machines

There is no information that Nystatin affects the ability to drive or operate machinery.

Important information about some of the ingredients of Nystatin

Auxiliary substance cetyl alcohol could cause local skin reactions.

3. HOW TO USE NYSTATIN

Take Nystatin ointment exactly as explained by your doctor. If you are not completely sure, check with your doctor or pharmacist.

Apply to the affected area 2 times a day or as needed to complete the healing.

This preparation does not color the skin and mucous membranes and is a simple and convenient method of treatment.

If you have any additional questions, please contact your doctor.

If you take more Nystatin than you should

If you have applied more of the medicine than recommended (overdose) you should not have any problems. If someone else takes your medicine, or you swallow the medicine (children), contact your doctor or the nearest medical facility. If swallowed, nystatin does not exceed in circulation, but it can cause stomach discomfort.

If you forget to take Nystatin

Never take a double dose to replace the missed dose of the medicine.

If you accidentally miss the daily dose, just take the next dose at the usual time.

If you suddenly stop taking Nystatin

You will not feel any changes if you abruptly stop taking the medicine.

If you have any questions relating to the use of Nystatin ointment, contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

As with the application of other medicines, prescribed dose of Nystatin ointment may cause side effects in a certain number of patients.

Nystatin ointment is practically non-toxic and does not cause increased sensitivity and is well tolerated by the patients of all ages, including newborns after severe birth, even after extended use of the medicine. In case of irritation, discontinue the use of the medicinal product.

If any of these side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE NYSTATIN

Shelf life: 3 (three) years.

Storage:

Keep at temperature up to 25 ° c.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What does Nystatin contain?

The active substance is:

1 g of ointment contains:

Nystatin 100.000 IU

The other ingredients are:

- cetyl alcohol;
- paraffin, light liquid;
- paraffin, white soft;
- white wax.

How Nystatin looks and contents of the Pack

Ointment is yellow in color.

The finished product (20g) is packed in aluminum tube with polypropylene cap.

The box contains one tube.

Regime of dispensing

The medicine is issued without the doctor's prescription

Manufacturer

Hemofarm proizvodnja farmaceutskih proizvoda d.o.o. Banja Luka
Novakovići bb, Banja Luka, Bosnia and Herzegovina

Manufacturer of the medicinal product

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