

Nystaland 100.000 IU/ML Oral Suspension

Nystatin 100.000 IU/ml



Read 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 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

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1. WHAT NYSTALAND ORAL SUSPENSION IS AND WHAT IT IS USED FOR

This medicine contains Nystatin as the active ingredient. Nystatin belongs to a group of medicines called antifungal antibiotics.

Nystatin Oral Suspension is used to prevent and treat fungal infections (thrush) of the mouth, throat or gut. It also provides effective prevention against oral thrush in those born of mothers with vaginal thrush. This medicine works by killing the yeast or fungus that has caused your symptoms.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NYSTALAND ORAL SUSPENSION

Do not take Nystaland Oral Suspension

- if you are allergic to Nystatin or any of the other ingredients of this medicine (listed in section 6).
Warnings and precautions.

Talk to your doctor or pharmacist before taking Nystaland Oral Suspension.

Talk to your doctor or pharmacist as Nystatin should not be used if you have a fungal infection in the lungs or on the skin (systemic mycoses).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. It is not known whether Nystatin can cause foetal harm when administered to a pregnant woman, however absorption of Nystatin from the gastro-intestinal tract is negligible, Nystatin should be prescribed during pregnancy only if the potential benefits outweigh the possible risks involved.

It is not known whether Nystatin is excreted in breast milk. Caution should be used when Nystatin is prescribed for nursing women.

Nystatin oral suspension contains methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed). Nystatin oral suspension contains small amounts of ethanol (alcohol), less than 100 mg per dose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE NYSTALAND ORAL SUSPENSION

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults and children is 1 ml of suspension dropped into the mouth four times a day. In the case of new-born babies, the recommended dose is 1 ml once a day dropped into the mouth.

Shake the bottle well before use. Use the measuring dropper provided.

Doses should be equally spaced throughout the day. If you are taking this medicine for an infection in the mouth or throat, try not to swallow the suspension too quickly, as the longer the medicine is in contact with the site of infection the better.

Your doctor will normally have given you sufficient medicine to enable you to continue treatment for 48 hours after all symptoms have disappeared. This will help to clear up your infection completely and prevent a relapse.

There are no specific dosage recommendations or precautions for the elderly.

If you take more Nystaland Oral Suspension than recommended, this should not cause any severe effects as the amount of Nystatin absorbed by the body is very small. With very high doses, nausea and gastrointestinal upset were reported. However, in the case of a child, you may wish to check with your doctor or hospital emergency department.

If you forget to take Nystaland Oral Suspension, take your medicine as soon as you remember, unless it is close to the time you would normally take your next dose. Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If irritation or sensitisation develops, treatment should be discontinued. Nausea has also been reported occasionally during therapy.

Large oral doses can occasionally cause:

- sickness and diarrhoea
- bloating
- stomach cramps, indigestion

Rash including urticaria (itching) have been reported rarely. Hypersensitivity, angioedema (swelling of the lips or tongue) and facial oedema (swelling of the face) have also been reported.

There have been very rare cases of a more serious allergic reaction called Steven-Johnson Syndrome (a serious illness with blistering of the skin, mouth, eyes and genitals).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE NYSTALAND ORAL SUSPENSION

Shake well before each use.

Do not use Nystaland Oral Suspension after the expiry date, which is stated on the carton and the bottle's label after EXP. The expiry date refers to the last day of that month.

Store below 25 °C. Protect from light.

Keep out of reach and sight of children.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Carton containing 1 amber glass bottle of 30 ml of Nystatin 100.00 IU/ml oral suspension, with leaflet. A graduated pipette marking 0.5 ml, included as cap. Nystaland Oral Suspension is a yellow to brownish suspension.

Composition: 100 ml of Nystatin oral suspension contain: Nystatin 10.000.000 IU (100,000 units per ml).
Excipients: sucrose, glycerol, ethanol 96°, disodium phosphate, orange flavour, methyl parahydroxybenzoate, polysorbate 20, xanthan gum, saccharin, sodium hydrogen carbonate, carmellose sodium, propyl parahydroxybenzoate and purified water.