

Package leaflet : Information for the patient
Nystan 100,000 units/ml Oral Suspension (Ready-Mixed)
Nystatin

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 Nystan Oral Suspension is and what it is used for**
- 2. What you need to know before you take Nystan Oral Suspension**
- 3. How to take Nystan Oral Suspension**
- 4. Possible side effects**
- 5. How to store Nystan Oral Suspension**
- 6. Contents of the pack and other information**

1. What Nystan Oral Suspension is and what it is used for

The name of this medicine is Nystan Oral Suspension. This medicine contains nystatin as the active ingredient.

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

Nystan 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 Nystan Oral Suspension

Do not take Nystan 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 Nystan Oral Suspension.

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

Other medicines and Nystan Oral Suspension

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 Nystan can cause harm to your unborn baby when taken by a pregnant woman or if Nystan can affect your ability to conceive, however absorption of Nystan from the digestive system is small.

It is not known whether Nystan is excreted in breast milk. Caution should be used when Nystan is given to women who are breast-feeding.

Driving and using machines

Nystan Oral Suspension should not affect your ability to drive.

Nystan Oral Suspension contains

Nystan Oral Suspension contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

Nystan Oral Suspension contains small amounts of ethanol (alcohol), less than 100mg per dose.

Nystan Oral Suspension contains less than 1 mmol sodium (23mg) per dose, i.e. essentially "sodium free".

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Nystan 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 1ml of suspension dropped into the mouth four times a day. In the case of newborn babies, the recommended dose is 1ml once a day dropped into the mouth.

There are no specific dosage recommendations or precautions for older people.

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. If signs and symptoms worsen or persist (beyond 14 days of treatment), you should talk to your doctor.

If you take more Nystan Oral Suspension than you should

Taking more Nystan Oral Suspension than recommended should not cause any severe effects as the amount of Nystan 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 Nystan Oral Suspension

If you forget to take Nystan 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).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

5. How to store Nystan Oral Suspension

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the bottle label and carton. This 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. These measures will help protect the environment.

6. Contents of the pack and other information

What Nystan Oral Suspension contains

- The active substance is nystatin, containing 100,000 units nystatin per ml.
- The other ingredients are: ethanol, flavours, glycerine, methyl parahydroxybenzoate (E218), pH adjusters (hydrochloric acid, sodium hydroxide), propyl parahydroxybenzoate (E216), sodium carboxymethylcellulose (E466), sodium phosphate, sucrose and water.

What Nystan Oral Suspension looks like and contents of the pack

Nystan Oral Suspension is supplied in a 30ml amber bottle. A graduated dropper is also included in the pack.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Vygoris Limited
930 High Road
London N12 9RT
United Kingdom
Tel: +44 (0) 1223 395301

Manufacturer:

Haupt Pharma Wolfratshausen GmbH
Pfaffenrieder Str. 5,
D-82515
Wolfratshausen, Germany

For any information about this medicine, please contact the Marketing Authorisation Holder.

The leaflet was revised in January 2019.