Package leaflet: Information for the user

Nystatin 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. See section 4.

What is in this leaflet

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

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

The name of this medicine is Nystatin Oral Suspension. This medicine contains nystatin as the active ingredient.
Nystatin belongs to a group of medicines called anti-fungal 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 Nystatin Oral Suspension

Do not take Nystatin 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 Nystatin 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).

Other medicines and Nystatin Oral Suspension
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

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

Driving and using machines
Nystatin Oral Suspension should not affect your ability to drive.

Nystatin Oral Suspension contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216), alcohol, sucrose (sugar) and is essentially "sodium free"
Nystatin Oral Suspension contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

This medicine contains 228 mg of alcohol (ethanol) in each 30 ml which is equivalent to 0.76 g in 100 ml. The amount in 1 ml of this medicine is equivalent to less than 0.2 ml beer or 0.1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

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

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

3. How to take Nystatin 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 newborn babies, the recommended dose is 1 ml once a day dropped into the mouth.
There are no specific dosage recommendations or precautions for older people.

Taking this medicine:
- Shake the bottle well before use.
- Use the measuring syringe provided, which is graduated in 0.5 ml steps.
- Doses should be equally spaced throughout the day.

A dosing syringe for oral administration graduated from 0.5 to 5 ml with an adapter to attach to the bottle is provided in the box.

On first use:
1. Remove the adapter from the syringe (see picture 1)
2. Remove the cap from the bottle
3. Insert the adapter into the bottle (see picture 2)
4. Close the bottle.

Each time you use it:
- Preparation of the delivery device
1. Shake the suspension before each use
2. Remove the cap from the bottle
3. Attach the syringe to the adapter (see picture 3)
4. Turn the vial/syringe assembly (see picture 4)
5. Fill the syringe with a small amount of medicine by pulling the plunger and then pushing the plunger upwards to avoid the formation of air bubbles.

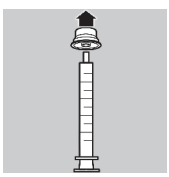
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Article code: P10013-01-A
CMO code: 85002368 Pharmacode number 1019

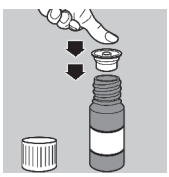
- Dose preparation
1. Make sure the plunger is at the bottom of the syringe (see picture 5)
2. Slowly pull the plunger to extract the required dose with the dosing syringe
3. Once the dose has been extracted, turn the vial/syringe assembly upside down and remove it by gently turning the syringe containing the dose to be administered.
4. Introduce the tip of the syringe directly into the mouth
5. Immediately administer the entire extracted volume by slowly pressing the plunger.

After each use:
1. Close the bottle with the cap, leaving the adapter in the bottle.
2. Rinse the syringe with water repeating the action.
3. Store the dry syringe in the box.

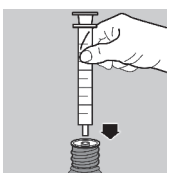
Never separate the dosing syringe from the other parts of the medicinal product package (box, package leaflet).



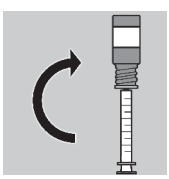
Picture 1



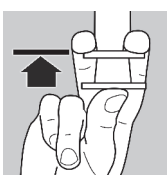
Picture 2



Picture 3



Picture 4



Picture 5

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 Nystatin Oral Suspension than you should

Taking more Nystatin Oral Suspension than recommended 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 Nystatin Oral Suspension

If you forget to take Nystatin 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

Rare side effects: may affect up to 1 in 1,000 people
- rash including urticaria (itching)
- hypersensitivy, and allergic reactions such as swelling of the lips or tongue and swelling of the face.

Very rare side effects: may affect up to 1 in 10,000 people
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Nystatin Oral Suspension

Keep this medicine out of the sight and reach of children.
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 store above 25°C.
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 Nystatin Oral Suspension contains
- The active substance is nystatin. Each ml of the suspension contains 100,000 units of nystatin.
- The other ingredients are ethanol, flavours*, glycerol, methyl parahydroxybenzoate (E218), pH adjusters (hydrochloric acid, sodium hydroxide), propyl parahydroxybenzoate (E216), carmellose sodium (E466), disodium phosphate, sucrose and water.

*cherry flavour, cinnamic aldehyde, peppermint oil.

What Nystatin Oral Suspension looks like and contents of the pack

Nystatin Oral Suspension is supplied in a bottle filled with 30 ml. A graduated syringe (in 0.5 ml steps) and an adapter are 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

Vetprom AD
The Vpharma site,
26 Otets Paisiy Str.,
Radomir, 2400, Bulgaria

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

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