

Nystimex 100000 IU/ml oral suspension

nystatin

Read all of this leaflet carefully before you start using 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 Nystimex is and what it is used for
2. What you need to know before you use Nystimex
3. How to use Nystimex
4. Possible side effects
5. How to store Nystimex
6. Contents of the pack and other information

1. What Nystimex is and what it is used for

Nystimex belongs to the group of antifungal medicines. It contains the active ingredient nystatin. It has a local effect on the mucosa and is not absorbed into the body.

Nystimex is used to treat fungal infections in the mouth and intestines.

2. What you need to know before you use Nystimex

Do not use Nystimex

- 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 using Nystimex.

Other medicines and Nystimex

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

Pregnancy, breast-feeding and fertility

Pregnancy

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 using this medicine.

You should only take this medicine if your doctor finds the benefits for you outweighing the potential risk for the foetus

Breast-feeding

It is not known whether Nystimex passes into breast milk. Consult your doctor before breast-feeding while taking this medicine.

Driving and using machines

There is no known effect of this medicine on the ability to drive or operate machinery.

Nystimex contains methyl parahydroxybenzoate and sodium

Methyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

This medicinal product contains 1.2 mg sodium per ml oral suspension, which is less than 23 mg per dose, i.e. essentially “sodium-free”.

3. How to use Nystimex

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

Your doctor or dentist decides the dose and it will be individualised for you.

The bottle should be shaken well before use.

Fungal infection of the oral cavity: The recommended dose for adults is 1 ml, 4 times daily. Take the suspension preferably after meals and keep it in your mouth for as long as possible before swallowing.

Use in children and infants

The recommended dose for children and infants is 1 ml, 4 times daily. Take the suspension preferably after meals and keep it in your mouth for as long as possible before swallowing. For infants, the suspension may be administered in drops or diluted with a little water and brushed in the mouth.

Fungal infection of the intestine: The recommended dose for adults is 5 ml 3 times daily. Swallow the suspension directly. To avoid the infection from returning, you should continue your treatment for 2-3 days after all signs of infection have disappeared.

Use in children and infants

The recommended dose for children and infants is 1 ml, 4 times daily. Swallow the suspension directly. To avoid the infection from returning, you should continue the treatment for 2-3 days after all signs of infection have disappeared.

If you use more Nystimex than you should

If you have used too much or a child has taken the medicine by mistake, contact your doctor or emergency unit for judgement of the risk and advice.

If you forget to use Nystimex

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.

Stop taking Nystimex and tell your doctor immediately if you develop any of these symptoms:

- Serious skin and mucosal changes (so called Stevens-Johnson syndrome).
This is a rare side effect and may affect up to 1 in 1000 people.
- Hypersensitivity reactions and local skin swelling (angioedema), a reaction in which the face and neck may swell considerably.
Hypersensitivity reactions from this medicine are very rare side effects (may affect up to 1 in 10,000 people) or not known (frequency can not be estimated from the available data)

Uncommon side effects (may affect up to 1 in 100 people):

- Allergic skin reactions.

High doses can cause stomach upset such as nausea, vomiting and diarrhoea.

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

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 [To be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nystimex

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

Store unopened bottles in a refrigerator (2°C – 8°C).

During the time of use it can be stored below 25° C for up to 1 month.

Do not use this medicine after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration in the medicine's appearance.

Do not throw away 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 Nystimex contains

- The active substance is nystatin. 1 ml of suspension contains 100,000 International Units (IU) of nystatin.
- The other ingredients are:
 - xylitol
 - carmellose sodium
 - methyl parahydroxybenzoate (E218)
 - peppermint oil
 - purified water.
- The oral suspension is sweetened with xylitol.

What Nystimex looks like and contents of the pack

Nystimex oral suspension is yellow and mint flavoured and comes in 100 ml amber glass bottles. In certain markets a 5 ml graded polyethylene/polystyrene syringe may be provided

Marketing Authorisation Holder

RPH Pharmaceuticals AB
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Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Nystimex 100 000 IE/ml oral suspension
Finland	Nystimex 100 000 IU/ml oraali suspensio
Iceland	Nystimex 100 000 a.e./ml mixtúra, dreifa
Netherlands	Nystatine RPH 100.000 IU/ml, suspensie voor oraal gebruik
Norway	Nystimex 100 000 IU/ml mikstur, suspenjon
Sweden	Nystimex 100 000 IE/ml oral suspension

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