
NYSTATIN DEVATIS 100,000 IU/mL Oral Drops

Ready mixed oral drops containing 100,000 IU nystatin per mL.

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about NYSTATIN DEVATIS 100,000 IU/mL Oral Drops. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

Please read this leaflet before you start taking NYSTATIN DEVATIS 100,000 IU/mL Oral Drops. If you are helping someone else take NYSTATIN DEVATIS 100,000 IU/mL Oral Drops, please read this leaflet before you give the first dose.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the expected benefits against possible risks of you using NYSTATIN DEVATIS 100,000 IU/mL Oral Drops they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What NYSTATIN DEVATIS 100,000 IU/mL Oral Drops is used for

NYSTATIN DEVATIS 100,000 IU/mL Oral Drops is the name of your antifungal medicine, which contains Nystatin. Nystatin is used to treat a condition called oral candidiasis or thrush. This is an infection in the mouth caused by the fungus *Candida* and is marked by sore, creamy-yellow, raised patches in the mouth.

NYSTATIN belongs to a group of medicines called antifungal agents. It works by damaging the cell wall of the *Candida* fungus, causing it to die. NYSTATIN DEVATIS 100,000 IU/mL Oral Drops only work inside the mouth, throat or gut. The amount of NYSTATIN absorbed into the bloodstream is minute and therefore is not effective for treating any other infections in the body.

Your doctor, however, may have prescribed NYSTATIN for another purpose. Ask your doctor if you have any questions about why NYSTATIN has been prescribed for you.

NYSTATIN is not addictive.

NYSTATIN is not expected to affect your ability to drive a car or operate machinery.

This medicine is available without a doctor's prescription. It can only be purchased at a pharmacy.

Before you take NYSTATIN DEVATIS 100,000 IU/mL Oral Drops

When you must not take it

Do not take NYSTATIN if you are allergic to nystatin or any of the ingredients listed at the end of this leaflet.

Do not use NYSTATIN if the packaging is torn or shows signs of tampering.

Do not use NYSTATIN after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not give NYSTATIN to children or infants unless your doctor tells you to.

Your doctor will check to make sure that NYSTATIN is the right treatment for your child's symptoms.

Before you start to take it

You must tell your doctor or pharmacist if:

1. You have any allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

2. You are pregnant or plan to become pregnant.

It is unlikely that NYSTATIN will harm your developing baby. However, it is recommended that you talk to your doctor about the risks and benefits of taking NYSTATIN during pregnancy.

3. You are breastfeeding or plan to breastfeed.

It is unlikely that NYSTATIN will pass into breast milk in sufficient amounts to affect your baby. However, it is recommended that you talk to your doctor about the risks and benefits of taking NYSTATIN when breastfeeding.

4. You have diabetes or any other medical condition.

People with diabetes are more likely to get thrush.

If you have not told your doctor or pharmacist about any of the above, tell them before you take any NYSTATIN.

NYSTATIN DEVATIS 100,000 IU/mL Oral Drops contains methylparaben (E218) and propylparaben (E216) which may cause allergic reactions (possibly delayed).

NYSTATIN DEVATIS 100,000 IU/mL Oral Drops contains small amounts of ethanol (alcohol), less than 100 mg per dose.

NYSTATIN DEVATIS 100,000 IU/mL Oral Drops contains less than 1 mmol sodium (23 mg) 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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

NYSTATIN does not usually interact with other medicines, but always tell your doctor about other medicines you are taking.

How to take NYSTATIN DEVATIS 100,000 IU/mL Oral Drops

NYSTATIN should be used only as directed by your doctor or pharmacist. It is important that you always follow your doctor or pharmacist instructions as they may differ from the information in this leaflet.

How much to take

Use the accompanying dropper with NYSTATIN to administer the dose.

The usual dose of NYSTATIN DEVATIS 100,000 IU/mL Oral Drops is 1 mL 4 times a day.
The same dose is given to infants, children and adults.

If your doctor or pharmacist tells you to take a different dose, follow their instructions.

How to take it

Shake the bottle well before use. Using the dropper provided, drop the required amount of suspension into the mouth. 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. Hold in your mouth or swish around for as long as possible before swallowing, as the longer the medicine is in contact with the site of infection the better.

After use replace the cap and wash the dropper in warm water and allow to dry (do not boil).

How long to take it

Your doctor or pharmacist 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 forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 0800 764 766) for advice, if you think that you or anyone else may have taken too much NYSTATIN. Do this even if there are no signs of discomfort or poisoning. Also report any other medicine or alcohol, which has been taken. You may need urgent medical attention. Keep telephone numbers for these places handy.

Taking more NYSTATIN DEVATIS 100,000 IU/mL Oral Drops than recommended should not cause any severe effects as the amount of NYSTATIN absorbed by the body is very small. If you take too much NYSTATIN (very high doses), you may get diarrhea, stomach upset, nausea and vomiting. However, in the case of a child, you may wish to check with your doctor or hospital emergency department.

While you are using NYSTATIN DEVATIS 100,000 IU/mL Oral Drops

Things you must do

Use NYSTATIN exactly as your doctor or pharmacist has recommended

Tell all doctors, dentists and pharmacists who are treating you that you are taking NYSTATIN.

If you become pregnant while you are taking NYSTATIN, tell your doctor

Tell your doctor or pharmacist if you feel NYSTATIN is not helping your condition.

See your doctor if symptoms persist or recur.

Your doctor will check your progress and see whether you need to keep taking NYSTATIN.

Always discuss with your doctor or pharmacist any problems or difficulties during or after taking NYSTATIN.

Tell your doctor or pharmacist if, for any reason, you have not taken your medicine exactly as recommended.

Otherwise your doctor or pharmacist may think that it was not effective and change your treatment unnecessarily.

Keep enough NYSTATIN to last weekends and holidays.

Things you must not do

Do not stop taking NYSTATIN or change the dose, without first checking with your doctor or pharmacist.

If you stop taking NYSTATIN or change the dose, NYSTATIN may not work as well.

Do not use this medicine to treat any other complaints unless your doctor or pharmacist says to.

Do not give NYSTATIN to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NYSTATIN DEVATIS 100,000 IU/mL Oral Drops.

NYSTATIN helps most people with thrush but it may have unwanted side effects in some people. As only small amounts of NYSTATIN are absorbed into the bloodstream, side effects are very rare.

All medicines may have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- feeling sick or nausea
- vomiting
- stomach upset
- diarrhea

These side effects are rare and usually occur if too much NYSTATIN is taken.

Rash including urticaria (itching) has been reported rarely. Hypersensitivity, angioedema (swelling of the lips or tongue) and facial edema (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 notice swelling of the face, mouth, lips, tongue or throat, or are feeling unwell after using NYSTATIN DEVATIS 100,000 IU/mL Oral Drops, stop using it and tell your doctor immediately, or go to the Accident and Emergency Centre at your nearest hospital.

If you experience these effects, you may have had a serious allergic reaction to NYSTATIN DEVATIS 100,000 IU/mL Oral Drops. You may need urgent medical attention. These side effects are very rare.

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell when you are taking, or soon after you have finished taking

NYSTATIN.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking NYSTATIN DEVATIS 100,000 IU/mL Oral Drops

Cleaning

After you have finish using the dropper, wash it with hot water. Keep the dropper away from other house utensils and crockery. This will help stop reinfection or the spread of infection to other household members.

Storage

Keep the drops in their bottle until it is time to take them.

If you take the drops out of the bottle they may not keep well.

Discard 14 days after opening.

Store NYSTATIN in a cool place where the temperature stays at or below 25°C.

Do not store it, or any other medicines, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one and- a-half meters above the ground is a good place to store medicines.

Disposal

Do not use NYSTATIN after the expiry date, which is stated on the packaging.

If your doctor or pharmacist advises you to stop taking NYSTATIN or the medicine has passed its expiry date, ask your pharmacist how to throw away medicines you no longer use. Do not throw away any medicines via wastewater. These measures will help protect the environment.

Product description

What it looks like

NYSTATIN DEVATIS 100,000 IU/mL Oral Drops is a light creamy, yellow, homogenous, cherry-peppermint flavored easily re-suspendable, particle-free opaque suspension.

Each 60 mL glass bottle contains 48 mL suspension. Bottles are packed in cardboard box with a graduated, plastic dropper with natural rubber teat.

Ingredients

Active ingredient:

The active ingredient in NYSTATIN DEVATIS 100,000 IU/mL Oral Drops is nystatin. Each 1 mL contains 100,000 units of nystatin.

Other ingredients:

Cinnamaldehyde, imitation cherry flavor, glycerol, methyl parahydroxybenzoate, propyl parahydroxybenzoate, peppermint oil, sucrose, carmellose sodium, disodium phosphate anhydrous, ethanol 96%, hydrochloric acid, purified water.

Sponsor



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