

NILSTAT®

Nystatin Oral Drops

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NILSTAT. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NILSTAT against the benefits 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 NILSTAT is used for

NILSTAT is a trade name for the antifungal medicine, 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.

NILSTAT is also used in infants to treat gut infections caused by *Candida*.

NILSTAT belongs to a group of medicines called antifungal agents. It works by damaging the cell wall of the *Candida* fungus, causing it to die. NILSTAT Oral Drops only work inside the mouth, throat or gut. The amount of NILSTAT 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 NILSTAT for another purpose. Ask your doctor if you have any questions about why NILSTAT has been prescribed for you.

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

Before you take NILSTAT

When you must not take it

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

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

Do not use NILSTAT 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 NILSTAT to children or infants unless your doctor tells you to.

Your doctor will check to make sure that NILSTAT 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 NILSTAT will harm your developing baby. However, it is recommended that you talk to your doctor about the risks and benefits of taking NILSTAT during pregnancy.

3. you are breastfeeding or plan to breastfeed.

It is unlikely that NILSTAT 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 NILSTAT 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 NILSTAT.

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.

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

How to take NILSTAT

NILSTAT 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 specially marked syringe provided with NILSTAT to measure the dose.

The usual dose of NILSTAT is 1mL four 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 measuring syringe provided, drop 1mL of suspension into the mouth. 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.

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

How long to take it

Continue taking NILSTAT until you have finished the bottle or until your doctor or pharmacist tells you to stop.

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 13 11 26) for advice, if you think that you or anyone else may have taken too much NILSTAT. 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.

If you take too much NILSTAT you may get diarrhoea, stomach upset, nausea and vomiting.

While you are using NILSTAT

Things you must do

Use NILSTAT exactly as your doctor or pharmacist has recommended

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

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

Tell your doctor or pharmacist if you feel NILSTAT 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 NILSTAT.

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

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

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

Keep enough NILSTAT to last weekends and holidays.

Things you must not do

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

If you stop taking NILSTAT or change the dose, NILSTAT 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 NILSTAT 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 using NILSTAT.

NILSTAT helps most people with thrush but it may have unwanted side effects in some people. As only small amounts of NILSTAT 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 if you notice any of the following and they worry you:

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

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

If you notice swelling of the face, mouth, lips, tongue or throat, or are feeling unwell after using NILSTAT 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 NILSTAT 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 NILSTAT.

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

After using NILSTAT

Cleaning

After you have finish using the syringe, wash it with hot water. Keep the dropper away from other house utensils and crockery. This will help stop re-infection 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.

Keep NILSTAT in a cool dry place where the temperature stays 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 metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking NILSTAT or the drops have passed their expiry date, ask your pharmacist what to do with any drops left over.

Product description

What it looks like

NILSTAT Oral Drops is a bright yellow coloured suspension with cherry flavour.

NILSTAT Oral Drops is supplied in a 24mL bottle with a separate measuring syringe.

Ingredients

The active ingredient in NILSTAT Oral Drops is nystatin.

Each 1mL contains 100,000 units of nystatin.

NILSTAT Oral Drops also contain the following inactive ingredients:

- sodium calcium edetate
- methyl hydroxybenzoate
- propyl hydroxybenzoate
- sucrose
- polysorbate 80
- bentonite
- hydrochloric acid
- sodium hydroxide
- cherry flavour
- purified water

The colouring agent in NILSTAT tablets is Quinoline Yellow CI 47005.

NILSTAT does not contain gluten, lactose, tartrazine or any other azo dyes.

Manufacturer

NILSTAT is supplied in Australia by:

Sigma Pharmaceuticals (Australia) Pty Ltd

(A.C.N. 004 118 594)

96 Merrindale Drive

Croydon Victoria 3136

Australia

Phone: (03) 9839 2800

Australian Registration Number:

NILSTAT Oral Drops

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