

NILSTAT

nystatin

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 used to treat a condition called intestinal candidiasis or thrush. This is an infection in your gut caused by the fungus *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 only works inside your gut. The amount of NILSTAT absorbed into the bloodstream is minute and therefore is not effective for treating any other infections in your body.

Your doctor, however, may have prescribed NILSTAT for another purpose. Ask your doctor if you have any questions about why this medicine is only available with a doctor's prescription.

It is not addictive.

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

Before you take it

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 it if the packaging is torn or shows signs of tampering.

Do not use it 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 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 this medicine 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.

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

Taking other medicines

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

NILSTAT is not known to interact with other medicines but your doctor still needs to know what other medicines you are taking.

How to take it

How much to take

The usual dose of NILSTAT is 1-2 tablets or capsules three times a day.

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

How to take it

Swallow tablets or capsules whole with a glass of water.

NILSTAT can be taken with or without food.

How long to take it

Continue taking NILSTAT until you have finished all the tablets or capsules in the bottle or until your doctor 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 it

Things you must do

Use NILSTAT exactly as your doctor 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 this medicine, tell your doctor.

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

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

Tell your doctor 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.

If you stop taking this medicine or change the dose, it may not work as well.

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

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

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking NILSTAT.

This medicine helps most people with *Candida* infections in the gut but it may have unwanted side effects in some people. As only minute 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 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.

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.

After using it

Storage

Keep your tablets or capsules in their bottle until it is time to take them.

If you take the tablets or capsules out of the bottle they may not keep well.

Keep your medicine 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 tells you to stop taking NILSTAT or the tablets or capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

NILSTAT Tablets are Round, biconvex, buff-coloured, film-coated tablets, approximately 3/8" (9.5mm) in diameter.

NILSTAT Tablets are supplied in an amber glass bottle containing 50 tablets.

NILSTAT Capsules are Size 2, opaque, buff-coloured capsules, printed "Nilstat" on cap and body in black ink, filled with a uniform, yellow, granular powder.

NILSTAT Capsules are supplied in a glass bottle containing 50 capsules.

Ingredients

The active ingredient in NILSTAT Tablets and Capsules is nystatin.

Each tablet or capsule contains 500,000 Units of nystatin.

NILSTAT Tablets also contain the following inactive ingredients:

- Lactose monohydrate
- Ethylcellulose
- Magnesium stearate
- Sodium starch glycolate
- Carnauba wax
- Purified water
- Opadry yellow OY-2144A.

The colouring agent in NILSTAT Tablets is Opadry yellow OY-2144A. It contains:

- Hypromellose
- Titanium dioxide
- Macrogol 400
- Iron oxide yellow CI 77492

NILSTAT Capsules also contain the following inactive ingredients:

- Lactose monohydrate
- Magnesium stearate
- Gelatin
- Iron Oxide yellow CI 77492
- Titanium dioxide
- Shellac
- Isopropyl alcohol

The ink printing on the capsule contains carbon black CI 77266 and ethanol.

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

Manufacturer

NILSTAT is supplied in Australia by:

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

Australian Registration Number:

NILSTAT Tablets
AUST R 15227

NILSTAT Capsules

AUST R 15228

This leaflet was revised in July 2020