

NILSTAT®

Nystatin Vaginal Cream and Cream Pessaries

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 using NILSTAT against the benefits they expect it will have for you.

If you have any concerns about using 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 vaginal infection called candidiasis or thrush. A fungus called Candida causes thrush. The symptoms of thrush include itching, burning and a thick, white "cottage cheese" discharge from the vagina.

Thrush is common in women of childbearing age or at menopause. It is more likely to occur if you are pregnant, menopausal, a diabetic, taking oral contraceptives (the 'Pill') or taking antibiotics. Though uncomfortable thrush is not usually serious.

Your doctor or pharmacist, however, may have recommended NILSTAT for another purpose. Ask your doctor or pharmacist if you have any questions about why

NILSTAT has been recommended for you.

NILSTAT belongs to a group of medicines called antifungal antibiotics. It works by killing the Candida fungus in your vagina. NILSTAT only works inside your vagina. It is not absorbed into the bloodstream and therefore is not effective for treating any other infections in your body.

NILSTAT is not addictive.

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

Before you use NILSTAT

When you must not use it

Do not use NILSTAT if you are allergic to NILSTAT 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 this medicine to children unless advised by the child's doctor.

Before you start to use 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.**

If you are pregnant you must not use the applicator provided with NILSTAT Vaginal cream. Ask your doctor how to apply NILSTAT.

It is unlikely that NILSTAT will harm your developing baby.

- 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**

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

How much to use

The usual dose is one full applicator of NILSTAT vaginal cream (5g) or 1 NILSTAT cream pessary (100,000 units), which is inserted

high into the vagina, once or twice daily.

How to apply it

For NILSTAT vaginal cream follow these instructions:

1. Remove cap from the tube
2. Turn cap upside down and use it to puncture the tube seal.
3. Screw the applicator onto the tube.
4. Squeeze the tube from the bottom forcing the cream into the cylinder.
5. Detach the applicator from the tube.
6. For easier insertion, of the applicator into the vagina, lie on your back with the knees bent and legs spread apart.
7. Spread the vaginal lips apart with one hand. Hold the filled applicator by the cylinder and gently insert it high into the vagina.
8. Press in the plunger and then with the plunger still depressed remove the applicator from the vagina holding it by the cylinder.
9. After each use wash the applicator with mild soap and water. It may be taken apart for easy cleaning. Do not boil. Rinse thoroughly.
10. Enclosed in your pack of NILSTAT Vaginal Cream are instructions on how to use the product, complete with diagrams.

For NILSTAT cream pessaries follow these instructions:

1. Moisten, but do not soak a pessary with lukewarm water.
2. Lie down on your back in a relaxed position. Bend knees and spread legs apart. Spread vaginal lips apart with one hand.
3. Insert the pessary high into the vagina using your index finger.

When to use it

NILSTAT is applied once or twice a day.

How long to use it

Do not use NILSTAT for longer than your doctor or pharmacist says.

You should start to feel more comfortable within 48 hours. NILSTAT is usually used for two weeks. However, sometimes you may need longer treatment.

You must see your doctor if you are not better after three days of treatment or if the symptoms return soon after finishing a course of treatment.

If you menstruate while using NILSTAT do not stop using it.

Having a period will not affect how well NILSTAT works.

If you forget to use 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 use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to casualty at your nearest hospital, if you think that you or anyone else may have taken NILSTAT or used 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.

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 using NILSTAT.

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

Tell your doctor 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 any problems or difficulties during or after using NILSTAT.

Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed.

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 use contraceptive diaphragms or condoms while using NILSTAT

The rubber may be damaged by NILSTAT.

If you are pregnant do not use cleansing douches while you are using NILSTAT.

Women who are not pregnant may use douches, but they are not necessary while you are using NILSTAT.

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

If you change the dose, NILSTAT may not work as well.

Do not stop using NILSTAT until healing is complete.

If you stop taking NILSTAT too early the infection may come back again.

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.

Things that may help your condition

If you find you get thrush easily, it is best to avoid nylon underwear, pantyhose and other tight fitting garments.

While you are using NILSTAT you may wish to wear sanitary protection as a normal hygiene measure.

Check with your doctor or pharmacist about whether it is a good idea to douche or have sexual intercourse while you are using NILSTAT.

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.

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:

- Vaginal irritation

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 using, or soon after you have finished using, NILSTAT.

Ask your doctor or pharmacist if you don't understand anything in this list.

After using NILSTAT

Cleaning the applicator

After each use wash the applicator.

The NILSTAT vaginal cream applicator may be taken apart for easier cleaning. Hold the barrel in one hand. Pull firmly on the plunger until comes out of the barrel. Wash the applicator with mild soap and warm water. Rinse thoroughly. Do not boil. The applicator does not have to be sterile.

To reassemble the applicator, push the plunger into the cylinder.

Storage

Keep your cream or pessaries in their packaging until it is time to take them.

If you take the cream or pessaries out of their 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 tells you to stop using NILSTAT or the cream or pessaries have passed their expiry date, ask your pharmacist what to do with any cream or pessaries left over.

Product description

What it looks like

NILSTAT vaginal cream is a smooth, pale yellow cream.

NILSTAT vaginal cream comes in a 75g tube with an applicator.

NILSTAT cream pessaries are oval, ivory coloured soft gelatin capsules.

NILSTAT cream pessaries come in a bottle containing 15 pessaries.

Ingredients

The active ingredient in NILSTAT is nystatin.

Each 5g NILSTAT vaginal Cream contains 100,000 units of nystatin.

Each NILSTAT cream pessary contains 100,000 units of nystatin.

NILSTAT vaginal cream contains the following inactive ingredients:

- purified water
- sodium hydroxide
- lactic acid
- sorbic acid
- glycerol
- isopropyl myristate
- emulsifying wax

NILSTAT cream pessaries contain the following inactive ingredients:

- isopropyl myristate
- paraffin - soft white
- emulsifying wax
- sorbic acid
- lactic acid
- gelatin
- titanium dioxide
- glycerol
- purified water
- methyl hydroxybenzoate

- propyl hydroxybenzoate

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

Manufacturer

NILSTAT is supplied in Australia by:

Wyeth Ayerst

Division of Wyeth Australia Pty
Limited

ABN 16 000 296 211

17-19 Solent Circuit

Baulkham Hills NSW 2153

AUSTRALIA

Telephone numbers:

(02) 9761 8200 or

(02) 8850 8200

For further information please
contact Wyeth Ayerst on toll-
free 1-800-500-498.

Australian Registration
Numbers

NILSTAT Vaginal Cream

AUST R 15103

NILSTAT Cream Pessaries

AUST R 15102

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