

CONSUMER MEDICINE INFORMATION



NYSTATIN ORAL DROPS

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. WHY AM I USING PHARMACY HEALTH NYSTATIN ORAL DROPS?

Pharmacy Health Nystatin Oral Drops contains the active ingredient nystatin. Pharmacy Health Nystatin Oral Drops is used to treat candidal infections of the mouth and throat (e.g. thrush).

For more information, see Section 1. Why am I using Pharmacy Health Nystatin Oral Drops? in the full CMI.

2. WHAT SHOULD I KNOW BEFORE I USE PHARMACY HEALTH NYSTATIN ORAL DROPS?

Do not use if you have ever had an allergic reaction to nystatin or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Pharmacy Health Nystatin Oral Drops? in the full CMI.

3. WHAT IF I AM TAKING OTHER MEDICINES?

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

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. HOW DO I USE PHARMACY HEALTH NYSTATIN ORAL DROPS?

- The dose for infants, children and adults is 1.0 mL to be taken 4 times daily.
- Use the dropper provided to measure the dose.
- Shake the bottle well before inserting the measuring dropper.
- Avoid taking food or drink for one hour after the dose.

More instructions can be found in Section 4. How do I use Pharmacy Health Nystatin Oral Drops? in the full CMI.

5. WHAT SHOULD I KNOW WHILE USING PHARMACY HEALTH NYSTATIN ORAL DROPS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist when you visit that you are using Pharmacy Health Nystatin Oral Drops.• Contact your doctor if symptoms persist or recur.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking Pharmacy Health Nystatin or alter the dose without checking with your doctor or pharmacist.
Drinking alcohol	<ul style="list-style-type: none">• Avoid taking drink for one hour after the dose.• Contact your doctor if you have taken alcohol. You may need urgent medical attention.
Looking after your medicine	<ul style="list-style-type: none">• Keep Pharmacy Health Nystatin in a cool dry place with temperature below 25°C.• Do not freeze.

For more information, see Section 5. What should I know while using Pharmacy Health Nystatin Oral Drops? in the full CMI.

6. ARE THERE ANY SIDE EFFECTS?

The side effects include feeling sick or nausea, vomiting, stomach upset, diarrhoea.

These side effects are rare and usually occur if too much Pharmacy Health Nystatin 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, Pharmacy Health Nystatin.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

PHARMACY HEALTH NYSTATIN ORAL DROPS

Active ingredient(s): *Nystatin*

CONSUMER MEDICINE INFORMATION (CMI)

This leaflet provides important information about using Pharmacy Health Nystatin Oral Drops. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Pharmacy Health Nystatin Oral Drops.**

Where to find information in this leaflet:

1. Why am I using Pharmacy Health Nystatin Oral Drops?
2. What should I know before I use Pharmacy Health Nystatin Oral Drops?
3. What if I am taking other medicines?
4. How do I use Pharmacy Health Nystatin Oral Drops?
5. What should I know while using Pharmacy Health Nystatin Oral Drops?
6. Are there any side effects?
7. Product details

1. WHY AM I USING PHARMACY HEALTH NYSTATIN ORAL DROPS?

Pharmacy Health Nystatin Oral Drops contains the active ingredient **nystatin**.

Pharmacy Health Nystatin Oral Drops is used to treat candidal infections of the mouth and throat (e.g. thrush)

Ask your pharmacist or doctor if you have any questions about this medicine. Your doctor may have given it for another reason.

2. WHAT SHOULD I KNOW BEFORE I USE PHARMACY HEALTH NYSTATIN ORAL DROPS?

Warnings

Do not use Pharmacy Health Nystatin if:

- you are allergic to Nystatin, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin
- you are giving it to children or infants unless your doctor tells you to. Your doctor will check to make sure that Pharmacy Health Nystatin is the right treatment for your child's symptoms.

Check with your doctor or pharmacist if you:

- have diabetes or any other medical condition. People with diabetes are more likely to get thrush.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

3. WHAT IF I AM TAKING OTHER MEDICINES?

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

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Pharmacy Health Nystatin Oral Drops.

4. HOW DO I USE PHARMACY HEALTH NYSTATIN ORAL DROPS?

How much to take

- The dose for infants, children and adults is 1.0 mL to be taken 4 times daily.
- Use the dropper provided to measure the dose.
- Do not exceed the recommended dosage.
- If your doctor or pharmacist tells you to take a different dose, follow their instructions.
- Take the medicine for at least for 48 hours after obtaining symptomatic relief.

How to take Pharmacy Health Nystatin Oral Drops

- Shake the bottle well before inserting the measuring dropper
- Fill the dropper to 1.0 mL mark.
- Squirt the medicine into your mouth and hold or swish around as long as possible before swallowing.
- Avoid taking food or drink for one hour after the dose.

If you forget to use Pharmacy Health Nystatin Oral Drops

If it is less than 1 hour before 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 your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your pharmacist or doctor.

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

If you use too much Pharmacy Health Nystatin Oral Drops

Taking an overdose of Pharmacy Health Nystatin may upset your stomach with nausea, vomiting and diarrhoea.

If you think that you have used too much Pharmacy Health Nystatin Oral Drops, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.
- Report if you have taken any other medicine or alcohol. You may need urgent medical attention.

You should do this even if there are no signs of discomfort or poisoning.

5. WHAT SHOULD I KNOW WHILE USING PHARMACY HEALTH NYSTATIN ORAL DROPS?

Things you should do

- Use Pharmacy Health Nystatin exactly as your doctor or pharmacist has recommended.
- Tell your doctor or pharmacist, if you feel Pharmacy Health Nystatin is not relieving your symptoms.
- Contact your doctor if symptoms persist or recur.
- Always discuss with your doctor or pharmacist any problems or difficulties during or after taking Pharmacy Health Nystatin.
- Tell your doctor or pharmacist if, for any reason, you have not taken your medicine exactly as recommended.

- Keep enough Pharmacy Health Nystatin to last weekends and holidays. Remind any doctor, dentist or pharmacist when you visit that you are using Pharmacy Health Nystatin Oral Drops.

Things you should not do

- Do not stop taking Pharmacy Health Nystatin or alter the dose without checking with your doctor or pharmacist.
- If you stop taking Pharmacy Health Nystatin or change the dose, Pharmacy Health Nystatin may not work as well.
- Do not use Pharmacy Health Nystatin Oral Drops to treat other complaints unless your doctor says to.
- Do not give Pharmacy Health Nystatin to anyone else, even if their symptoms seem similar to yours.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Looking after your medicine

- Keep Pharmacy Health Nystatin Oral Drops in the bottle until it is time to use.
- If you take the medicine out of the bottle before it is time to use, it may not keep well.
- Keep Pharmacy Health Nystatin in a cool dry place with temperature below 25°C.
- Do not freeze.
- A locked cupboard at least one and a half meters above the ground is a good place to keep the medicines.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

When to discard your medicine

Discard the medicine after 4 weeks of opening.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

If your doctor or pharmacist tells you to stop taking Pharmacy Health Nystatin Oral Drops or the drops have passed the expiry date, ask your pharmacist what to do with any drops left over.

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

6. ARE THERE ANY SIDE EFFECTS?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • feeling sick or nausea, • vomiting, • stomach upset, • diarrhoea 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you. These side effects are rare and usually occur if too much Pharmacy Health Nystatin is taken.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. PRODUCT DETAILS

This medicine is available over-the-counter from a pharmacist without a doctor's prescription.

What Pharmacy Health Nystatin Oral Drops contains

Active ingredients (main ingredients)	Nystatin
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • sucrose • saccharin sodium • carmellose sodium • sodium citrate dihydrate • sodium hydroxide • methyl hydroxybenzoate • propyl hydroxybenzoate • purified water • vanilla flavour cream 9/H07915

Do not take this medicine if you are allergic to any of these ingredients.

What Pharmacy Health Nystatin Oral Drops looks like

Pharmacy Health Nystatin Oral Drops is a vanilla flavoured yellowish suspension.

Each 1mL contains 100,000 international units of Nystatin.

Pharmacy Health Nystatin Oral Drops is supplied in a 24mL bottle with a separate measuring dropper.

Who distributes Pharmacy Health Nystatin Oral Drops

Pharmacy Health
250 Camberwell Road,
Camberwell, Victoria
3124, Australia

For Medical enquiries: 1800 497 206

For General enquiries: 1300 363 303

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