

## MYCOSTATIN® Oral Drops

Nystatin 100 000 IU/mL

### Consumer Medicine Information

#### What is in this leaflet

##### Read this leaflet carefully before taking MYCOSTATIN Oral Drops.

This leaflet answers some common questions about MYCOSTATIN Oral Drops. It does not contain all the available information. Some of the information contained in this leaflet may not apply to you. It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Always follow the instructions that your doctor or pharmacist give you about MYCOSTATIN Oral Drops.

##### Keep this leaflet with the medicine.

You may need to read it again.

#### What MYCOSTATIN Oral Drops is used for

MYCOSTATIN is a trade name (manufacturer's name) for the antifungal medicine, Nystatin. Nystatin is used to treat oral infections caused by a family of yeast-like fungi called Candida. This condition is known as oral candidiasis or thrush.

MYCOSTATIN Oral Drops are used to treat thrush in the mouth, tongue or throat.

MYCOSTATIN Oral Drops only kill yeast belonging to the Candida family as well as some other types of fungi. It does not cure infections caused by bacteria or viruses.

This medicine is available from your pharmacist and does not require a prescription.

#### Before you take MYCOSTATIN Oral Drops

Before buying this product, make sure that you tell your pharmacist what symptoms you are experiencing. Your pharmacist will then advise you whether MYCOSTATIN Oral Drops is the most suitable medicine for your condition.

##### When you must not take MYCOSTATIN Oral Drops

**Do not take MYCOSTATIN Oral Drops if you have an allergy to nystatin or to any ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include:

- swelling of the face, tongue, mouth, lips, throat and difficulty breathing
- severe and sudden onset of hives or a skin rash.

##### Do not take it after the expiry date printed on the back of the pack.

If this medicine is used after the expiry date has passed, it may not work as well.

##### Do not take MYCOSTATIN Oral Drops if the packaging is torn or shows signs of tampering.

*Before you start to take Mycostatin Oral Drops*

**Tell your doctor or pharmacist if you have allergies to:**

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

**Tell your doctor or pharmacist if you are pregnant or intend to become pregnant**

There is no evidence that it is harmful to take MYCOSTATIN Oral Drops while you are pregnant. However your doctor or pharmacist will discuss with you the possible risks and benefits of using Mycostatin Oral Drops during pregnancy.

##### Tell your doctor or pharmacist if you are breast-feeding or planning to breast-feed.

Your doctor or pharmacist will discuss with you the possible risks and benefits of using Mycostatin Oral Drops during breast feeding.

If you have not told your doctor or pharmacist about any of the above, tell them before you start to take MYCOSTATIN Oral Drops.

##### Taking other medicines

**Tell your pharmacist if you are taking other medicines, including vitamin and herbal supplements or any medicines you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines may affect the way others work. Your pharmacist may have more information on medicines to be careful with or to avoid while using MYCOSTATIN Oral Drops.

#### How to take MYCOSTATIN Oral Drops

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

##### How much to take

Take 1 mL [100,000 International Units] of MYCOSTATIN Oral Drops four times a day.

##### How to take it

1. Measure 1 mL of MYCOSTATIN Oral Drops using the graduated dropper provided in the carton.
2. Release the medicine directly from the dropper into the mouth. Keep the oral drops in the mouth as long as possible before swallowing.
3. Wash the dropper with hot water. Return dropper to bottle and tighten the lid. If you do not understand the instructions on how to take MYCOSTATIN Oral Drops, ask your pharmacist for help.

##### When to take MYCOSTATIN Oral Drops

You may take MYCOSTATIN Oral Drops at any time. It is recommended, however, that you take it at about the same time each day. Taking MYCOSTATIN at the same time may help you remember when to take the Oral Drops.

##### How long to take it

It is usual to continue taking the oral drops for at least two days after the infection has gone to make sure it doesn't return

##### If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the 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 missed dose.

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

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

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

##### If you take too much (overdose)

**Immediately call your doctor or the Poisons Information Centre on 131126, or go to the Accident and Emergency Centre at your nearest hospital if you or anyone else takes too much MYCOSTATIN. Do this even if there are no signs of discomfort or poisoning.**

#### While you are taking MYCOSTATIN

##### Things you must do

If you are about to start taking any new medicines, tell all doctors and pharmacists who are treating you that you are using MYCOSTATIN Oral Drops.

If you become pregnant while using MYCOSTATIN Oral Drops, tell your doctor or pharmacist.

If you plan to have surgery, tell your doctor or dentist that you are using MYCOSTATIN Oral Drops.

If your symptoms do not improve after several days of treatment or they return soon after completing your course of treatment, tell your doctor.

##### Things you must not do

Do not give MYCOSTATIN Oral Drops to anyone else, even if they have the same condition as you.

Do not take MYCOSTATIN Oral Drops to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop using MYCOSTATIN Oral Drops until the infection is cured.

##### Things to be careful of

To avoid the possibility of re-infection or infection of other household members, you must observe strict personal hygiene. Hands must be washed thoroughly before and after administering the drops.

Wash used kitchen utensils by boiling for 20 minutes. Wash your used utensils separately and keep them away from utensils used by other household members. This may help prevent spread of the infection.

#### Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MYCOSTATIN Oral Drops.**

MYCOSTATIN Oral Drops helps most people with oral thrush infections, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Ask your pharmacist or doctor to answer any questions you may have.

**If you notice swelling of the face, mouth, lips, tongue or throat, or are feeling unwell after using MYCOSTATIN 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 MYCOSTATIN Oral Drops. You may need urgent medical attention. These side effects are very rare.

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

- loose bowel motions or diarrhoea
- indigestion or upset stomach
- nausea
- vomiting.

These are the more common side effects of MYCOSTATIN Oral Drops.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell. Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## After using MYCOSTATIN Oral Drops

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### *Cleaning*

After you have finished using the dropper, 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*

Store MYCOSTATIN Oral Drops in a cool dry place where the temperature stays below 25°C.

Do not store MYCOSTATIN or any other medicine in the bathroom or near the kitchen sink. Do not leave it in the car on hot days. 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 MYCOSTATIN Oral Drops, or the Drops have passed their expiry date, ask your pharmacist what to do with any that is left over.

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## Product description

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### *What it looks like*

MYCOSTATIN Oral Drops is a light creamy yellow coloured suspension.

### *Ingredients*

**Each mL of Mycostatin Oral Drops contains:**

**Active ingredients: 100,000 IU Nystatin**

**Other ingredients:**

sugar, glycerol, sodium saccharine, carmellose sodium, sodium phosphate - dibasic, methyl and propyl paraben, ethyl alcohol, Cherry flavour, peppermint oil, cinnamaldehyde and water.

### *Manufacturer*

Mycostatin Oral Drops are manufactured and distributed in Australia by:

Bristol-Myers Squibb Australia Pty Ltd

A.C.N. 004 333 322

556 Princes Highway

NOBLE PARK, VIC 3174

Australia

### *Registration number*

AUST R 19220

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