

**PACKAGE LEAFLET:  
INFORMATION FOR THE USER**

**MYCOSTATIN® 100,000 units/ml  
ORAL SUSPENSION (Ready mixed)  
(nystatin)**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you**

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, ask your doctor or pharmacist.**
- **This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.**
- **If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.**

The name of your medicine is Mycostatin 100,000 units/ml oral suspension (Ready mixed) but it will be referred to as Mycostatin Oral Suspension throughout this leaflet.

**What is in this leaflet:**

1. What Mycostatin Oral Suspension is and what it is used for
2. What you need to know before you take Mycostatin Oral Suspension
3. How to take Mycostatin Oral Suspension
4. Possible side effects
5. How to store Mycostatin Oral Suspension
6. Contents of the pack and other information

**1. What is Mycostatin Oral Suspension and what it is used for**

The name of this medicine is Mycostatin Oral Suspension. This medicine contains nystatin as the active ingredient.

Nystatin belongs to a group of medicines called anti-fungal antibiotics.

Mycostatin Oral Suspension is used to prevent and treat fungal infections (thrush) of the mouth, throat or gut. This medicine works by killing the yeast or fungus that has caused your symptoms.

**2. What you need to know before you take Mycostatin Oral Suspension**

**Do not take Mycostatin Oral Suspension:**

- If you are allergic to nystatin or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**

- Talk to your doctor or pharmacist before taking Mycostatin Oral Suspension if you have a fungal infection in the lungs or on the skin (systemic mycoses), as Mycostatin should not be used for these types of infections.

**Other medicines and Mycostatin Oral Suspension**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

**Pregnancy and breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**

Mycostatin Oral Suspension should not affect your ability to drive.

Please note that this medicine contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause (possibly delayed) allergic reactions.

This medicinal product contains small amounts of ethanol (alcohol), less than 100mg per dose.

This medicinal product contains less than 1mmol sodium (23mg) per dose, i.e. essentially "sodium free".

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Mycostatin oral suspension may be harmful to the teeth.

**3. How to take Mycostatin Oral Suspension**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults and children is 1ml of suspension dropped into the mouth four times a day. In the case of newborn babies, the recommended dose is 1ml once a day dropped into the mouth.

Shake the bottle well before use.

Use the measuring dropper provided. Doses should be equally spaced throughout the day.

If you are taking this medicine for an infection in the mouth or throat, try not to swallow the suspension too quickly, as the longer the medicine is in contact with the site of infection the better.

Your doctor will normally have given you sufficient medicine to enable you to continue treatment for 48 hours after all symptoms have disappeared. This will help to clear up your infection completely and prevent a relapse.

There are no specific dosage recommendations or precautions for the elderly.

**If you take more Mycostatin Oral Suspension than you should**

Taking more Mycostatin Oral Suspension than recommended should not cause any severe effects as the amount of Mycostatin absorbed by the body is very small. With very high doses, nausea and gastrointestinal upset were reported. However, in the case of a child, you may wish to check with your doctor or hospital emergency department.

## If you forget to take Mycostatin Oral Suspension

If you forget to take Mycostatin Oral Suspension, take your medicine as soon as you remember, unless it is close to the time you would normally take your next dose. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If irritation or sensitisation develops, treatment should be discontinued.

Patients treated with Mycostatin have reported the following side effects:

Uncommon side effects (between 1 in 100 and 1 in 1000 people):

- Diarrhoea
- Stomach cramps and indigestion
- Feeling sick (nausea) and being sick (vomiting)
- Skin rash

Rare side effects (between 1 in 1000 and 1 in 10,000 people):

- Swelling of the face, lips, or tongue
- Stevens-Johnson syndrome (blistering of the skin, mouth, eyes and genitals)
- Itching

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

### 5. How to store Mycostatin Oral Suspension

Keep out of the sight and reach of children.

Do not store above 25 °C. Do not freeze.

Store in the original container.

The shelf life after opening the bottle when kept under the conditions of temperature listed above is 7 days.

Do not use if you notice any visible signs of deterioration. (For e.g.: change in the appearance of the suspension or its colour, odour or taste).

Do not use after the expiry date which is stated on the carton and bottle ('Exp'). The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### 6. Further information

#### What Mycostatin Oral Suspension contains

Mycostatin Oral Suspension contains nystatin as the active ingredient. Each ml of oral suspension contains 100,000 units nystatin.

The other ingredients are sucrose, ethanol (96%), carmellose sodium, cinnamic aldehyde, peppermint essence, imitation cherry flavour, anhydrous sodium hydrogen phosphate, glycerol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), hydrochloric acid, sodium hydroxide and purified water.

## What Mycostatin Oral Suspension looks like and contents of the pack

Mycostatin Oral Suspension is in the form of opaque light creamy yellow suspension, smell and taste of cherry-mint with bitter aftertaste.

Each pack contains one bottle with 60ml of suspension. A graduated dropper is also included in the pack.

**Manufactured by:** Haupt Pharma Wolfratshausen GmbH, Pfaffenrieder Str. 5, D-82515, Wolfratshausen, Germany.

**Procured from within the EU and repackaged by the PPA holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**MYCOSTATIN® 100,000 units/ml ORAL SUSPENSION (Ready Mixed)**

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**POM**

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