

**Package leaflet: Information for the patient**  
**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.

**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 Mycostatin Oral Suspension is 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. 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.

It is not known whether Mycostatin can cause harm to your unborn baby when taken by a pregnant woman or if Mycostatin can affect your ability to conceive, however absorption of Mycostatin from the digestive system is small.

It is not known whether Mycostatin is excreted in breast milk. Caution should be used when Mycostatin is given to women who are breast-feeding.

### **Driving and using machines**

Mycostatin Oral Suspension should not affect your ability to drive.

### **Mycostatin Oral Suspension contains**

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 newborns (from birth to 1 month) is 1ml three times a day dropped into the mouth.

The recommended dose for infants (1 month to 2 years) is 1 to 2ml four times a day.

The recommended dose for children (over 2 years) and adults is 1 to 6ml four times a day.

There are no specific dosage recommendations or precautions for older people.

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, 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. If signs and symptoms worsen or persist (beyond 14 days of treatment), you should talk to your doctor.

**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: may affect up to 1 in 100 people

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

Rare: may affect up to 1 in 1,000 people

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

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Mycostatin Oral Suspension**

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not freeze.

Store in the original container.

Do not use this medicine after the expiry date which is stated on the label, carton and bottle. The expiry date refers to the last day of that month

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Mycostatin Oral Suspension contains**

- The active substance is nystatin, containing 100,000 units nystatin per ml.
- The other ingredients are: cherry flavour, cinnamic aldehyde, ethanol, glycerol, methyl parahydroxybenzoate (E218), peppermint oil, pH adjusters (hydrochloric acid, sodium hydroxide), propyl parahydroxybenzoate (E216), sodium carboxymethylcellulose (E466), anhydrous disodium phosphate, sucrose and purified water.

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

Mycostatin Oral Suspension is supplied in a 30ml amber bottle. A graduated dropper is also included in the pack.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder:**

Bristol-Myers Squibb  
Pharmaceuticals Ltd.,  
Swords, County Dublin.  
Ireland  
Tel: 1 800 749 749

#### **Manufacturer:**

Haupt Pharma Wolfratshausen  
GmbH Pfaffenrieder  
Str. 5, D-82515 Wolfratshausen,  
Germany

For any information about this medicine, please contact the Marketing Authorisation Holder.

**This leaflet was revised in June 2017.**