

**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 ethanol, sucrose, sodium, propyl parahydroxybenzoate (E216) and methyl parahydroxybenzoate (E218)**

This medicine contains 182 mg of alcohol (ethanol) in 24 ml (corresponding to 6 ml four times daily; 24 ml is the maximum dose delivered) which is equivalent to 0.76 g in 100 ml. The amount in 24 ml of this medicine is equivalent to less than 4.6 ml of beer or 1.8 ml of wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 0.5 g of sucrose per ml. This should be taken into account in patients with diabetes mellitus.

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

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

This medicine contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause (possibly delayed) allergic reactions.

### **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 1 ml three times a day dropped into the mouth.

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

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

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

Shake the bottle well before use.

Use the measuring syringe provided, which is graduated in 0.5 ml steps.

Doses should be equally spaced throughout the day.

A dosing syringe for oral administration graduated from 0.5 to 5 ml with an adapter to attach to the bottle is provided in the case.

**On first use:**

1. Remove the adapter from the syringe (see picture 1)
2. Remove the cap from the bottle
3. Insert the adapter into the bottle (see picture 2)
4. Close the bottle.

**Each time you use it:**

- Preparation of the delivery device

1. Shake the suspension before use ensuring the cap is closed prior to shaking
2. Remove the cap from the bottle
3. Attach the syringe to the adapter (see picture 3)
4. Invert the vial/syringe assembly (see picture 4)
5. Fill the syringe with a small amount of medicine by pulling the plunger and then pushing the plunger upwards to avoid the formation of air bubbles.

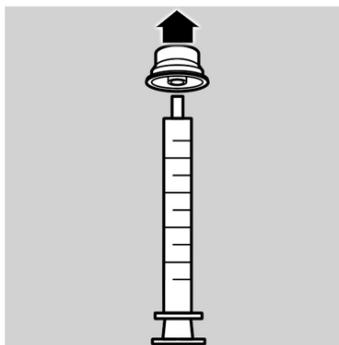
- Dose preparation

1. Ensure the plunger is pushed in fully to the bottom of the syringe (see picture 5)
2. Slowly pull the plunger to extract the required dose with the dosing syringe
3. Once the dose has been measured, revert the vial/syringe assembly to an upright position and remove the syringe containing the dose to be administered by gently turning
4. Introduce the tip of the syringe directly into the mouth
5. Immediately administer the entire measured dose by slowly pressing the plunger.

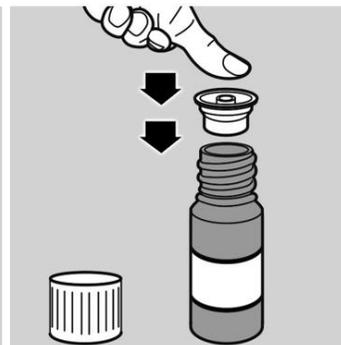
**After each use:**

1. Close the bottle with the cap, leaving the adapter in the bottle.
2. Rinse the syringe with water repeating the action.
3. Store the dry syringe in the box.

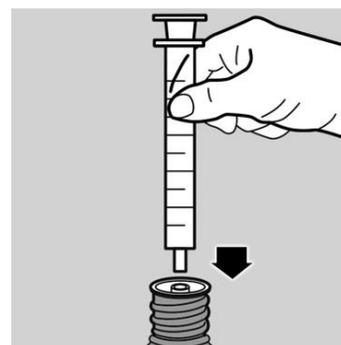
Never separate the dosing syringe from the other parts of the medicinal product package (box, package leaflet).



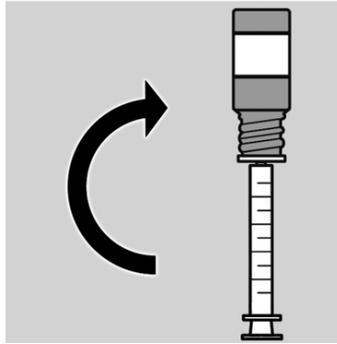
Picture 1



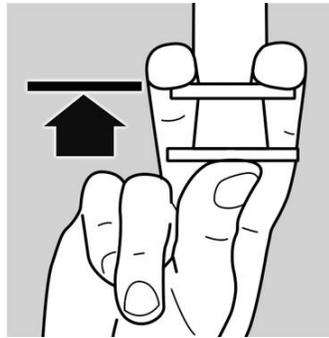
Picture 2



Picture 3



Picture 4



Picture 5

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 bottle filled with 30 ml. A graduated syringe (in 0.5 ml steps) and an adapter are also included in the pack.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder:**

Substipharm  
24 Rue Erlanger  
75016 Paris  
France  
Tel: 1800300170

### **Manufacturer:**

Vetprom AD  
The Vpharma site,

26 Otets Paisiy Str.,  
Radomir, 2400,  
Bulgaria

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

**This leaflet was revised in July 2023.**