

Package leaflet: Information for the patient

Mycoren Suspension Nystatin BP 100,000 I.U

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

- a. What Mycoren Oral Suspension is and what it is used for
- b. What you need to know before you take Mycoren Oral Suspension
- c. How to take Mycoren Oral Suspension
- d. Possible side effects
- e. How to store Mycoren Oral Suspension
- f. Contents of the pack and other information

a. What Mycoren Oral Suspension is and what it is used for

The name of this medicine is Mycoren Oral Suspension. This medicine contains nystatin as the active ingredient. Nystatin belongs to a group of medicines called anti-fungal antibiotics. Mycoren Oral Suspension is used to prevent and treat fungal infections (thrush) of the mouth, throat or gut. It also provides effective prevention against oral thrush in those born of mothers with vaginal thrush. This medicine works by killing the yeast or fungus that has caused your symptoms.

b. What you need to know before you take Mycoren Oral Suspension

Do not take Mycoren Oral Suspension:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Mycoren Oral Suspension.

Talk to your doctor or pharmacist as Mycoren should not be used if you have a fungal infection in the lungs or on the skin (systemic mycoses).

Other medicines and Mycoren 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 Mycoren can cause harm to your unborn baby when taken by a pregnant woman or if Mycoren can affect your ability to conceive, however absorption of Mycoren from the digestive system is small.

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

Driving and using machines

Mycoren Oral Suspension should not affect your ability to drive.

Mycoren Oral Suspension contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free". If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

c. How to take Mycoren Oral Suspension

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

Oral Candidiasis

Infants (1 month to 2 years)

1ml should be dropped into the mouth four times a day.

Children (≥ 2 years) and adults

For the treatment of denture sores, and oral infections in children (≥ 2 years) and adults caused by candida albicans. 1ml of the suspension should be dropped into the mouth four times daily; it should be kept in contact with the affected areas as long as possible.

Intestinal candidiasis

Infants (1 month to 2 years)

1ml should be dropped into the mouth four times a day.

Adults

For the treatment of intestinal candidosis 5ml of the suspension should be dropped into the mouth four times daily.

Paediatric population (≥ 2 years)

1ml should be dropped into the mouth four times a day.

For prophylaxis a total daily dosage of 1 million units has been found to suppress the overgrowth of candida albicans in patients receiving broad-spectrum antibiotic therapy.

For prophylaxis in the newborn the suggested dose is 1ml once daily.

The longer the suspension is kept in contact with the affected area in the mouth before swallowing, the greater will be its effect.

Administration should be continued for 48 hours after clinical cure to prevent relapse.

Older people

No specific dosage recommendations or precautions.

If signs and symptoms worsen or persist (beyond 14 days of treatment), the patient should be reevaluated, and alternate therapy considered.

If you take more Mycoren Oral Suspension than you should

Taking more Mycoren Oral Suspension than recommended should not cause any severe effects as the amount of Mycoren 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 Mycoren Oral Suspension

If you forget to take Mycoren 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.

d. 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. Nausea has also been reported occasionally during therapy.

Large oral doses can occasionally cause:

- sickness and diarrhoea
- bloating
- stomach cramps, indigestion

Rash including urticaria (itching) have been reported rarely. Hypersensitivity, angioedema (swelling of the lips or tongue) and facial oedema (swelling of the face) have also been reported. There have been very rare cases of a more serious allergic reaction called StevenJohnson Syndrome (a serious illness with blistering of the skin, mouth, eyes and genitals).

e. How to store Mycoren Oral Suspension

Do not store above 30°C. Protect from light.

Keep out of reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label and carton.

This 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 protect the environment.

f. Contents of the pack and other information

What Mycoren Oral Suspension contains

The active substance is nystatin, containing 100,000 IU nystatin per ml.

The other ingredients are: Bronopol, Sodium Saccharin, Carmellose Sodium, Propylene Glycol, Disodium EDTA, Sucrose and Tutti Frutti Flavour

What Mycoren Oral Suspension looks like and contents of the pack

Mycoren Oral Suspension is supplied in 30 ml amber glass bottle.

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A milestone to Golden Health