

Nystatin Oral Suspension

Nystatin

Please read this leaflet carefully before you start to take your medicine. It contains important information.

- Keep the leaflet in a safe place because you may want to read it again.
- If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Nystatin Oral Suspension is and what it is used for
2. Before you take Nystatin Oral Suspension
3. How to take Nystatin Oral Suspension
4. Possible side effects
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6. Further Information



1 What Nystatin Oral Suspension is and what it is used for

Nystatin Oral Suspension contains the active ingredient nystatin which belongs to a group of medicines known as anti-fungal antibiotics.

It is used for the prevention and treatment of infections of the mouth, throat and intestinal tract caused by a fungus called Candida. It also provides effective protection against Candida infection in children born to mothers with vaginal Candida infection.

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2 Before you take Nystatin Oral Suspension

Do not take Nystatin Oral Suspension if you are:

- allergic to Nystatin or any of the other ingredients in the product (see Section 6: 'What Nystatin Oral Suspension contains').

Take special care with Nystatin Oral Suspension

Children must not be given the medicine if they have a sugar intolerance.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Nystatin should only be prescribed during pregnancy if your doctor thinks its necessary. It is not known whether nystatin gets into breast-milk therefore, ask your doctor for advice before taking any medicine.

Driving and using machines

Nystatin Oral Suspension is not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Nystatin Oral Suspension

The product contains:

- **Sucrose** - contains 0.2g of sucrose per 1 ml dose. If you know you have an intolerance to some sugars, contact your doctor before taking this medicine. Nystatin Oral Suspension should not be given to children with disaccharide intolerance.
- **Propyl-p-hydroxybenzoate (E216) and methyl-p-hydroxybenzoate (E218)** - may cause allergic reactions such as nettle rash and wheezing, as well as delayed skin type reactions.
- **Sodium metabisulphite (E223)** - may rarely cause severe hypersensitivity reactions and bronchospasm (difficulty in breathing).
- **Sodium** - this medicinal product contains 0.3 mmol (or 1.3 mg) sodium per 1 ml dose. To be taken into consideration by patients on a controlled sodium diet.

3 How to take Nystatin Oral Suspension

Always take Nystatin Oral Suspension exactly as your doctor has told you. Do not use the suspension if the seal is broken. Do not dilute the medicine. Shake the medicine well before use. **Hold the medicine in the mouth and keep in contact with the affected area(s) for as long as possible before swallowing.**

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The usual doses are as follows:

Adults and the elderly	
<i>Denture sores and mouth infections caused by Candida albicans:</i>	1 ml, 4 times a day.
<i>Gut infections:</i>	5 ml, 4 times a day.
<i>Prevent candidal infection/overgrowth:</i>	If you are also taking other antibiotics, a total daily dosage of 10 ml will probably be sufficient.
Children	
<i>Intestinal and mouth infections caused by Candida albicans in infants and children:</i>	1 ml, 4 times a day.
<i>Protection against infection in newborn babies</i>	1 ml, once a day.

You should continue to take Nystatin Oral Suspension for 48 hours after your infection has cleared. This is important to prevent the infection returning.

If you take more Nystatin Oral Suspension than you should

One extra dose is unlikely to be a cause for concern but if you, or someone else, have accidentally taken too much suspension, contact your doctor or local hospital accident and emergency department immediately.

If you forget to take Nystatin Oral Suspension

If you miss a dose, take the medicine as soon as you remember and continue your next dose as usual. Do not take a double dose to make up for the one forgotten.

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

4 Possible side effects

Like all medicines, Nystatin Oral Suspension can cause side effects, although not everybody gets them.

Side effects when taking nystatin are unusual, except if taking large doses of 40-50 ml daily.

Stop taking this medicine and contact your doctor or the nearest hospital immediately if you experience any of the following:

- Severe itchy skin rash, swelling of the hands, face, lips or tongue, or difficulty breathing.
- Stevens-Johnson Syndrome (symptoms include cough, aches, headache, fever, vomiting, diarrhoea, rash and blisters).

Other reported symptoms:

- feeling sick (nausea), being sick (vomiting).
- mouth irritation and sensitisation.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5 How to store Nystatin Oral Suspension

Keep out of the reach and sight of children.

Store this product in a cool place, but do not freeze.

Do not take Nystatin Oral Suspension after the expiry date stated on the label.

Do not use the suspension if the seal is broken or if you notice any visible signs of deterioration.

Ask your pharmacist how to dispose of medicines no longer required.

6 Further information

What Nystatin Oral Suspension contains

The **active ingredient** is nystatin. Each 1ml of suspension contains 100,000 International Units (IU) of nystatin.

The **other ingredients** are: sodium carboxymethylcellulose, methyl-p-hydroxybenzoate, propyl-p-hydroxybenzoate, sodium metabisulphite, sucrose, saccharin sodium, sodium citrate, aniseed flavour and purified water (*see also end of Section 2: 'Important information about some of the ingredients of Nystatin Oral Suspension'*).

What Nystatin Oral Suspension looks like and contents of the pack


The medicine contains 30ml of suspension, in a brown glass bottle with either a plastic cap or a child-resistant cap.

Marketing Authorisation Holder and Manufacturer

Sandoz Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, UK.

This leaflet was last approved in 03/2011 (to be amended after approval).

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