

TYSTATIN ORAL SUSPENSION®

Nystatin (100,000 units per ml)

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What Tystatin is used for

Tystatin contains the active ingredient nystatin.

Nystatin is available as a 100,000 units/mL oral suspension. It is used to prevent and treat fungal infections of the mouth (thrush) that caused by a fungus called Candida.

How Tystatin works

Nystatin belongs to a group of medicines called anti-fungal antibiotics. It works by interfering with their cell membranes and thus kill the fungi and treats the infection.

Before you use Tystatin

- When you must not use it

- Have ever had allergic reaction to nystatin, the active ingredient, or to any of the excipients.

- Before you start to use it

Tell your doctor if you:

- Have allergies to any other medicines, food, preservatives or dyes
- Have a fungal infection in the lungs or on the skin
- Are pregnant, planning to become pregnant, or are breast-feeding.

If you are not sure whether you should start taking this medicine, consult your doctor.

- Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription. You may need to use different amounts of these medicines, or you may need to take different medicines.

- Pregnancy and lactation

If you are pregnant or breast-feeding, think that are pregnant or are planning to be

pregnant, ask your doctor or pharmacist for advice before taking this medicine. It is not known whether nystatin can cause foetal harm when administered to a pregnant woman. Nystatin should only be prescribed during pregnancy if your doctor thinks it is necessary.

It is not known whether nystatin gets into breast milk therefore, ask your doctor for advice before taking this medicine.

How to use Tystatin

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Shake the bottle well before use, then draw up the correct amount into the measuring dropper provided.

The suspension should be swished throughout or be retained in the mouth for as long as possible before swallowing. Individuals should avoid taking food or drink earlier than one hour after a dose. In infants and young children, apply one half of dose in each side of mouth.

The dosage should be continued for 48 hours after lesions have resolved.

- How much to use

Children and Adults

One to six ml (100,000 to 600,000 units) four times daily after food.

Infants

One ml (equivalent to 100,000 units) four times daily after food.

- When to use it

Take your medicine as directed by your doctor or pharmacist. Do not use the suspension if the seal is broken. Shake well before use.

- How long to use it

The duration of treatment will depend on the infection you have. Individuals with severe infections may require long term treatment to prevent the infection from returning. If you do not complete the full course prescribed by your doctor, the infection may not

completely clear or your symptoms may return.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Nausea and gastrointestinal discomfort may develop in overdosage of exceeding 5 million units of nystatin.

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

While you are using it

- Things you must do

- Always take Tystatin exactly according to the instructions given to you by your doctor or pharmacist. If you are unsure, check with your doctor or pharmacist.
- Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Tystatin.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects gets serious or anything else that make you feel unwell.
- Inform your doctor immediately if you are pregnant or planned to get pregnant while taking Tystatin.

- Things you must not do

- Do not give this medication to anyone else, even if they have the same condition as you.
- Do not stop taking your medicines without consulting your doctor. It is important to

keep taking your medicine even if you feel well.

- Do not use Tystatin after the expiry date which is stated on the carton and bottle.

- Things to be careful of

Be careful driving or operating machinery until you know how this drug affects you.

Taking Tystatin may cause nausea or vomiting. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Although Tystatin is relatively well tolerated and adverse effects are not common, they can occur.

The following adverse effects have been reported with Tystatin Oral Suspension:

- Nausea, vomiting, diarrhoea, stomach upset, and stomach pain

- Altered taste and decreased appetite

If mouth irritation develops, treatment should be discontinued.

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)

Above are serious but rare side effects. You may need urgent medical attention.

Tell your doctor or pharmacist if you notice anything else that makes you feel unwell.

Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public -> Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety)

Storage and Disposal of Tystatin

Storage

Store below 30°C in a well-closed container. Do not freeze and protect from light.

Do not store Tystatin or any other medicines in the bathroom, near a sink or leave it at the window sill or in the car.

Keep out of reach and sight of children.

- Disposal

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.

Product Description

- What it looks like

Tystatin Oral Suspension is a yellow suspension with a raspberry-vanilla flavour.

- Ingredients

- Active ingredient

Each ml contains 100,000 units of nystatin.

- Inactive ingredients

Polyethylene glycol 1500, microcrystalline cellulose, glycerin, carboxymethylcellulose sodium, saccharin sodium, polysorbate 80, purified water, raspberry essence and vanilla flavor. Methyl paraben and propyl paraben as preservatives.

- Packing

It is supplied in bottles of 12ml, 30ml and 60ml.

- MAL Number

MAL20032250AZ

Manufacturer

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Product Registration Holder

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