

MIKOSTAT ORAL SUSPENSION

Nystatin (100,000 IU/ml)

What is in this leaflet:

1. What Mikostat is used for
2. How Mikostat works
3. Before you use Mikostat
4. How to take Mikostat
5. While you are using it
6. Side effects
7. Storage and Disposal of Mikostat
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Mikostat is used for:

Mikostat Oral Suspension is indicated for the treatment of fungal infections in the oral cavity.

How Mikostat works:

Nystatin is the active ingredient of Mikostat. Nystatin works by killing the *Candida* fungus causing the mouth infection.

Before you use Mikostat

- When you must not take it

Do not take Mikostat if you are allergic to Nystatin or any of the ingredients in the product.

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

Do not take Mikostat if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Mikostat.

- Before you start to use it:

Mikostat should not be used if you have a fungal infection that is spreading throughout the body (systemic mycoses).

If irritation or sensitization develops, treatment should be discontinued.

- Taking other medicines

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

This includes those medicines that you buy without a prescription. Your doctor will be able to tell you if any problems could occur when taking Mikostat with other medicines.

How to use Mikostat

Always take Mikostat exactly as your doctor has told you. Do not use the suspension if the seal is broken.

- How much to use

Children and Adults:

1 to 6 mL (100,000 to 600,000 units nystatin) four times daily.

The suspension should be retained in the mouth for several minutes before swallowing.

In young children, apply one-half of dose in each side of mouth.

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

- When to use it

Take Mikostat as recommended by your doctor

- How long to use it

Mikostat should be continued for at least 48 hours after symptoms have disappeared.

- If you forget to use it

Take the missed dose as soon as you remember. Do not try to make up for missed doses by taking more than one at a time.

- If you use too much (overdose)

Immediately telephone your doctor or go to the emergency department at your nearest hospital if you or anyone else has taken a large amount of Mikostat. Do this even if there are no signs of discomfort or poisoning. Be sure to show the doctor the Mikostat packaging.

While you are using it

- Things you must do

Take Mikostat exactly as your doctor has prescribed.

Good oral hygiene, especially the proper care of dentures is important.

Keep any follow up appointments with your doctor. It may be necessary to make sure that Mikostat works well.

- Things you must not do

Pregnancy and breast-feeding

Mikostat should only be taken during pregnancy if your doctor thinks it's necessary.

Nursing Mothers

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

Do not give this medicine to anyone else, even they have the same condition as you. Ask your doctor or pharmacist for advice before taking any medicine.

- Things to be careful of

Please seek for your doctor's or pharmacist's advice first before taking this medicine.

Side effects

Mikostat is usually well – tolerated.

At high doses, gastrointestinal disturbances such as nausea, vomiting and diarrhoea have occasionally been experienced.

Oral irritation and sensitization, rash (including urticaria) and a rarely, serious skin reaction such as blistering of the skin, mouth, lips, eyes and genitals (Stevens-Johnson syndrome) have been reported after oral administration of nystatin.

Tell the doctor about any effect which is troublesome or ongoing.

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

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 portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Mikostat

- Storage

Keep medicine out of the reach and sight of children.

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

Heat and dampness can destroy some medicines

Keep your medicine in the original container.

If you take it out of its original container, it may not keep well.

Store at temperature below 25°C.

- 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

Light mustard to dark mustard colour, homogenous suspension having caramel-toffee flavor with sweet agreeable taste.

- Ingredients

- Active ingredient

Nystatin.

Each 1ml contains Nystatin 100,000 IU.

- Inactive ingredients

The other ingredients are Sucrose, Methyl paraben, Propyl paraben, Sorbitol, Avicel, Glycerol, CMC sodium, Tween 80, Sodium saccharin, Caramel-toffee flavor, Ethanol, Sodium hydroxide, Hydrochloric acid and Purified water.

- MAL number:

MAL07124631AZ

Manufacturer

Gulf Pharmaceutical Industries (Julphar)
Digdaga, Airport Street
P.O.Box 997,
Ras Al Khaimah,
United Arab Emirates

Product Registration Holder

Averroes Pharmaceuticals Sdn. Bhd.
11E, Level 5, Block 1
Worldwide Business Center
Jalan 13/50, Section 13
40000 Shah Alam, Selangor
Malaysia

Date of revision

29/07/2015

Serial Number:

BPFK(R4/1)240715/00223