PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is to be supplied by doctor's prescription only

NYSTATIN READY MIX
Oral Suspension

The active ingredient and its quantity:

Each ml suspension contains:

Nystatin 100,000 IU

For a list of inactive ingredients, please see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

1. What is the medicine intended for?

For treatment of oral fungal infections.

Therapeutic group: anti-fungal.

2. Before using the medicine:

X Do not use this medicine if:

You are sensitive (allergic) to Nystatin or any of the other ingredients of this medicine (listed in section 6).

⚠ Special warnings regarding the use of the medicine:

- **Before treatment with Nystatin, tell the doctor if:**
  - You suffer from a fungal infection in the lungs or on the skin (systemic mycoses) - Do not use Nystatin in this case.

⚠ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

⚠ Pregnancy, breast-feeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to get pregnant, you should consult a doctor or pharmacist before taking this medicine.

It is not known whether Nystatin may cause harm to the fetus due to the use during pregnancy or if Nystatin can affect the ability to conceive, however absorption of Nystatin from the digestive system is small.

It is not known whether Nystatin is excreted in breast milk. Caution should be used when considering administration of Nystatin to women who are breast-feeding.

⚠ Driving and operating machinery:

Nystatin should not affect your ability to drive.

⚠ Important information about some of the medicine's ingredients:

The medicine contains methyl paraben and propyl paraben which may cause allergic reactions (possibly delayed).

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

3. How should you use the medicine?

Always use according to the doctor's instructions. You should check with the doctor or pharmacist if you are uncertain.

The dosage and manner of treatment will be determined by the doctor only. The standard dosage is usually:

Newborns (from birth to the age of 1 month) – 1 ml four times a day.

Infants and children up to the age of 5 (from the age of 1 month to 5 years) - 2 ml (1 ml for each side of the mouth), four times a day.

Children over 5 years and adults – 4-6 ml (half dose for each side of the mouth), four times a day.

Elderly: There are no special warnings and no dose adjustment is required.

Do not exceed the recommended dose.

Shake the bottle well before use.

This medicine is to be taken at specific time intervals as determined by the attending doctor. Doses should be equally spaced throughout the day.

If you are taking the medicine for the treatment of infection in the area of the mouth or throat, hold the suspension in the oral cavity for as long as possible prior to swallowing in order to enable longer contact with the affected area.

The doctor will usually provide you with an amount of medicine which will enable you to continue the treatment for another 48 hours after the symptoms have disappeared to enable complete cure of the infection and to prevent its recurrence.

If symptoms worsen or persist (beyond 14 days of treatment), you should consult the doctor.

If you have accidentally taken a higher dose, no severe effects should occur since the amount of Nystatin absorbed in the body is very small.

At very high doses, nausea and gastrointestinal disturbances have been reported.

If you have taken an overdose, or if a child has accidentally swallowed an overdose of the medicine, refer immediately to a doctor or to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take this medicine at the required time, take a dose as soon as you remember, unless it is almost time for the next dose. Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding the use of this medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, use of Nystatin may cause side effects in some users. Do not be alarmed by reading the list of side effects. You might not suffer from any of them.

If irritation or sensitisation develops, treatment should be discontinued. Nausea has also been reported occasionally during therapy.

Large 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.

Very rare cases of a more serious allergic reaction called Steven-Johnson Syndrome (a serious illness with blistering of the skin, mouth, eyes and genitals) have been reported.

If any side effect appears, if any of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health (MoH) by clicking on the "Report on side effects due to medication therapy" link on the MoH home page (www.health.gov.il) which refers to the online form for side effects reporting.

5. How to store the medicine?

- This medicine should be kept in a safe place out of the reach and sight of children and/or infants.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- 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. Further information

In addition to the active ingredient, this medicine also contains:

Sucrose, sorbitol solution 70%, propylene glycol, aluminium hydroxide gel, methyl paraben, cinnamaldehyde, anethole, sodium saccharine, propyl paraben, purified water.

Each 1 ml of the medicine also contains: Sugar 500 mg, Sodium 0.06 mg.

What does the medicine look like and what are the contents of the package:

A yellow suspension in a 30 ml glass vial with a pipette.

Manufacturer and license holder: Taro Pharmaceutical Industry Ltd., 14 Hakitor Street, Haifa Bay 2624761.

This leaflet was checked and approved by the Ministry of Health in March 2016.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 12350.25007