**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

This medicine is dispensed with a doctor's prescription only

# NYSTATIN READY MIX
**Suspension**

**Active ingredient**
Each ml of suspension contains 100,000 units nystatin.

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

## 1. What is this medicine intended for?

For the treatment of oral fungal infections.
**Therapeutic group:** anti-fungal.

## 2. Before using this medicine:

**Do not use this medicine if:**

- You are sensitive (allergic) to nystatin or to any of the other ingredients in this medicine (see section 6).

**Special warnings about using this medicine**

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

**Drug interactions**

**If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.**

**Pregnancy, breastfeeding and fertility**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Pregnancy and fertility
It is not known whether Nystatin Ready Mix can cause harm to your unborn baby when taken by a pregnant woman or if Nystatin Ready Mix affect your ability to conceive, however absorption of Nystatin Ready Mix from the digestive system is small.

Breastfeeding
It is not known whether Nystatin Ready Mix excreted in breast milk. Caution should be used when Nystatin Ready Mix is given to women who are breastfeeding.

**Driving and using machines**
Nystatin Ready Mix should not affect your ability to drive.

**Important information about some of this medicine's ingredients**
The medicine contains methyl paraben and propyl paraben which may cause allergic reactions (possibly delayed).
The medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free".

The medicine contains sucrose and sorbitol. Sorbitol is a source of fructose. If you have been told by your doctor that you have intolerance to some sugars, or if you have been diagnosed with hereditary fructose intolerance, a rare genetic disorder in which a person cannot break down fructose, contact your doctor before taking this medicine. Sucrose may harm your teeth when used for two or more weeks.

## 3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

**Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:**
Newborns (from birth to the age of 1 month) – 1 ml or a dropper filled to the cap four times a day.
Older babies and children up to the age of 5 (from the age of 1 month to 5 years) - 1 ml or a dropper filled to the cap on each side of the mouth, four times a day.
Children over 5 years and adults – 2-3 ml or two to three droppers filled to the cap on 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 times as determined by your doctor. Doses should be equally spaced throughout the day.
If you are taking the medicine to treat an infection in the mouth or the throat, hold the suspension in the oral cavity for as long as possible prior to swallowing to enable longer contact with the affected area.
Your doctor will normally have given you sufficient medicine to enable you to continue treatment for 48 hours after all symptoms have disappeared. This will help to clear up your infection completely and prevent a relapse.
If symptoms worsen or persist (beyond 14 days of treatment), you should consult your doctor.

**If you have accidentally taken a higher dose,** no severe effects should occur as the amount of nystatin absorbed by the body is very small. With very high doses, nausea and gastrointestinal disturbances were reported. If a child has accidentally taken an overdose, see a doctor or go to a hospital emergency room.

**If you forget to take the medicine at the scheduled 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 as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

**Do not take medicines in the dark! Check the label and the dose every time you take medicine. Wear glasses if you need them.**
**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

## 4. Side effects

Like with all medicines, using Nystatin Ready Mix may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience 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 Stevens-Johnson syndrome (a serious illness with blistering of the skin, mouth, eyes and genitals) have been reported.

**If you experience any side effect appears, if any side effects get worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

## 5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this medicine and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25˚C.
- May be used for 3 months after first opening.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to discard the medicine (medicines you no longer use). These measures will help protect the environment.

## 6. Additional 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.

**What the medicine looks like and contents of the pack:**
A yellow suspension in a 30 ml glass bottle with a dropper.

**Manufacturer and registration holder's name and address:** Taro Pharmaceutical Industry Ltd., 14 Hakitor Street, Haifa Bay 2624761.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 123-50-25007-00

Revised in December 2022 according to MOH guidelines.