

**Patient leaflet in accordance with the Pharmacists' Regulations
(Preparations) - 1986**

This medicine is dispensed without a doctor's prescription

Pitriya-T

Name of active ingredient and concentration per dosage unit:

terbinafine hydrochloride 1% w/w

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.

Use this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Consult your doctor if your symptoms of illness get worse or do not improve within one week.

1. What is the medicine intended for?

This medicine is a broad-spectrum antifungal agent for the treatment of fungal infections of the skin.

Therapeutic group: antifungal.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine.

Special warnings about using this medicine

Before starting treatment with Pitriya-T tell your doctor if you have any other disease or any allergies.

- Pitriya-T is not recommended for use in children under 12 years old.
- This medicine is intended for external use only. Avoid contact with the eyes. In case of contact with eyes, immediately rinse your eyes thoroughly with running water. Consult your doctor if you feel any discomfort.
- Consult your doctor if you have widespread fungus on your foot or if the fungal infection also affects your nails.
- Do not apply any other medicines to the treated areas on your skin.

Children and adolescents

There is no information about the safety and efficacy of using this medicine in children under 12 years old.

Drug interactions

If you are taking or have recently taken other medicines, including

nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding, think you are pregnant, or are planning a pregnancy, consult your doctor or pharmacist before using this medicine. Do not use this medicine if you are pregnant, unless advised to by your doctor. Do not use this medicine if you are breastfeeding, and avoid contact of infants with any areas treated with this medicine.

Driving and using machines

Pitriya-T has no effect on the ability to drive and operate machines.

Important information about some of this medicine's ingredients

Pitriya-T contains cetyl alcohol and stearyl alcohol which may cause local skin irritation such as eczema (contact dermatitis). A 15 gram pack of this medicine contains 150 mg benzyl alcohol and a 30 gram pack contains 300 mg benzyl alcohol, which is equivalent to 10 mg/gram. Benzyl alcohol can cause allergic reactions and local skin irritation.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Before using Pitriya-T, rinse the affected area and dry it thoroughly.

You may apply Pitriya-T once or twice a day (morning and/or evening). Gently apply a thin layer of Pitriya-T on the affected area and around it.

The recommended dosage is usually:

Fungal infection of the foot between the toes (tinea pedis), fungal infection of the groin, fungal infection of the body - apply once a day for one week.

Fungal infection of the foot on the sole and/or sides of the foot (plantar-type tinea pedis (moccasin type)) - apply twice a day for two weeks.

Skin candidiasis - once to twice a day, for one week.

Pityriasis versicolor (sun fungus (scaly skin)) - apply once to twice a day, for two weeks.

Treat the fungal infection according to the dosages listed in this leaflet. Consult your doctor or pharmacist if you feel that the effect of this medicine is too strong or too weak.

If there is no improvement in your condition within a week, consult your doctor.

Do not exceed the recommended dose.

Do not swallow. For external use only. Apply the cream for the recommended period even if your condition seems to improve after a few days. You will usually see an improvement within a few days, but the infection may reappear if the cream is not applied as recommended or for the recommended duration.

If treating skin folds, the area may be covered with a gauze strip, especially at night. The gauze should be replaced with every application. Wash your hands every time you apply the cream to the affected area.

How can you help your treatment succeed?

To prevent a fungal infection in the foot, do as follows:

- Change clothing that has been in contact with the affected area every day.
- Avoid wearing close-fitting clothing or clothing that prevents ventilation of the skin.
- Gently dry the affected area after washing it.
- Change your towel every day.
- If you have a fungal infection of the foot, do not walk around barefoot. In addition, powder or spray your shoes with foot antifungal products. To prevent spreading the infection, wash your hands thoroughly after use and contact with the affected skin.

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

If you have swallowed some medicine, contact your doctor who will advise you what to do.

If you forget to apply the medicine at the scheduled time, do not apply a double dose. Apply the next dose at the usual time and consult your doctor.

Do not take medicines in the dark! Check the label and 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 Pitriya-T may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop using this medicine and contact your doctor immediately if you experience any of the following effects which could indicate an allergic reaction:

- difficulty breathing and swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with redness or raised blisters.

Side effect frequencies:

Very common side effects - affect more than 1 in 10 users

Common side effects - affect 1-10 in 100 users

Uncommon side effects - affect 1-10 in 1,000 users

Rare side effects - affect 1-10 in 10,000 users

Very rare side effects - affect less than 1 in 10,000 users

Side effects of unknown frequency (the frequency of these effects has not been established yet)

Side effects of the immune system:

Very rare: hives

Side effects of the eyes:

Rare: irritation

Side effects of the skin:

Common: peeling, itching

Uncommon: sores, scabs, skin disorders, skin color changes, redness, burning sensation

Rare: dryness, eczema, contact dermatitis (on contact with the medicine)

Very rare: rash or pimples on the skin

General side effects and side effects in the treated area:

Uncommon: pain, pain or irritation in the treated area

Rare: worsening fungal infection

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

Reporting side effects:

You can report side effects to the Ministry of Health 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 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.

Storage conditions:

Store below 25°C.

Shelf-life after first opening: 12 months after first opening the tube.

6. Additional information

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

purified water, isopropyl myristate, cetyl alcohol, stearyl alcohol, polysorbate 60, benzyl alcohol, sorbitan monostearate, cetyl palmitate, sodium hydroxide.

What the medicine looks like and contents of the pack -

Pitriya-T is a smooth white cream. The cream is marketed in packs of 15 and 30 grams. Not all pack sizes may be marketed.

Registration holder's name and address: Taro International Ltd., 14 Hakitor Street, Haifa Bay 2624761.

Manufacturer's name and address: Taro Pharmaceuticals Inc., 130 East Drive,
Brampton, Ontario, Canada.

This leaflet was revised in December 2021 according to MOH guidelines.

**Registration number of the medicine in the Ministry of Health's National Drug
Registry:** 166-65-36323-00.