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

The medicine is dispensed without a doctor's prescription

# Pitrex®

## Cream

**Composition:**
Tolnaftate 1% w/w

For information on the inactive and allergenic ingredients, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Further Information".

**Read the 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.

Use this preparation according to the instructions in the dosage section of this leaflet. Consult a pharmacist if you need further information.
Refer to a doctor if the symptoms of the disease are not improving after 10 days.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

Cream for topical treatment of superficial fungal skin diseases.

**Therapeutic group:** Topical antifungal.

### 2. BEFORE USING THE MEDICINE

**☒ Do not use the medicine:**
- If you are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine. See section 6 "Further Information".
- To treat nail or scalp infections.

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

**❗ Important information about some of the ingredients of the medicine**
The preparation contains butylated hydroxytoluene (E 321), which may cause a localized skin reaction (e.g., contact dermatitis) or irritation of the eyes or mucous membranes.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

**The usual dosage is generally:**
Apply a thin layer on the affected area 2-3 times a day.
**Do not exceed the recommended dose.**

**This medicine is not generally intended for children and infants under two years of age.**
If there is no improvement in your condition within 10 days, refer to a doctor.

- Do not swallow.
- For external use only.
- Avoid contact with the eyes.

**How can you contribute to the success of the treatment?**
Humidity promotes the growth of fungi; therefore, the affected area should be kept dry.
Wash the affected area before each application of the medicine.
When treating the feet, it is important to wash and dry them thoroughly, especially between the toes. It is best to wear cotton socks. Avoid wearing socks made of wool or synthetic materials. It is advisable to change them several times a day (depending on the amount of sweat). During the appropriate seasons, it is advisable to wear sandals without socks.

**If a child accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.**

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**
**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

### 4. SIDE EFFECTS

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

**Stop using the medicine if the following side effects worsen:**
- Occasional itch, irritation or rash.

**Additional side effects**
Side effects of unknown frequency (effects whose frequency has not been determined):
- Skin reactions, contact dermatitis.

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

**Reporting side effects**
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicines, should be kept in a safe place, out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- 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 in a cool place, below 25°C.**
- **After first opening, can be used up to the expiry date that appears on the package.**

### 6. FURTHER INFORMATION

**In addition to the active ingredient, the medicine also contains:**
Polyethylene glycol 400, polyethylene glycol 4000, white petrolatum, titanium dioxide, butylated hydroxytoluene (E 321).

**What the medicine looks like and the contents of the package:**
A smooth white cream. Each package contains 15 g cream in an aluminum tube.

**Name of Manufacturer and License Holder and its Address:**
Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 026.52.21118

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health in November 2011 and was updated in accordance with the Ministry of Health guidelines in January 2020.