

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

The medicine is dispensed without a doctor's prescription

## **AGISTEN PASTE**

### **Clotrimazole 1% W/W**

Inactive and allergenic ingredients in the preparation - see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

**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.

Use this medicine in the correct manner. Consult the pharmacist if you need further information. Refer to the doctor if symptoms of the illness worsen or if they do not improve after 7 days.

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

For the treatment of abrasions and skin infections caused by species of fungi sensitive to clotrimazole.

**Therapeutic group:** An antifungal preparation from the imidazole group.

### **2. BEFORE USING THE MEDICINE:**

#### **Do not use the medicine:**

- if you or your child are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine.
- for treatment of infections of the scalp or nails.

#### **Special warnings regarding use of this medicine:**

- As with other oily preparations, such as creams and Vaseline, Agisten Paste may lower the effectiveness of rubber contraceptives, such as a condom or diaphragm. Therefore, if the medicine is intended for use on the genitals, use an alternative contraceptive for at least five days after using this medicine.
- Do not use this medicine frequently or for a prolonged period without consulting a doctor.
- Do not use on open wounds.
- Avoid contact between the preparation and the eyes and mouth. In case of contact with the eyes or mouth, wash thoroughly with water and refer to a doctor.

#### **Before treatment with Agisten Paste, tell the doctor if:**

- You are not sure if you (or your baby, in case of diaper rash) have a fungal infection.
- The patient is sensitive to any food or medicine.

#### **If you or your child are taking, or have recently taken, other medicines,**

including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

#### **Pregnancy and breastfeeding:**

If you are pregnant, trying to become pregnant, or are breastfeeding, consult with a doctor or with the medical staff before using the medicine.

If you have already informed the doctor/medical staff, carefully follow their instructions.

#### **Important information about some of the ingredients of the medicine**

Agisten Paste contains wool fat, which may cause localized skin effects (e.g., contact dermatitis).

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

Check with the doctor or pharmacist if you are uncertain. If the medicine was prescribed for you by a doctor, follow his/her instructions.

If you purchased the medicine without a prescription, carefully follow the following instructions:

- **The usual dosage** is generally: apply 2-3 times a day to the affected area.

#### **Instructions for use:**

Apply a thin and even layer of paste on clean, dry, and aired skin and gently massage into the skin. Usually, a small amount of a length of ½ cm of paste is enough to cover an area the size of a palm.

The duration of treatment depends on the type of infection. In general, at least two weeks of use are necessary; however, 4 weeks of treatment may be necessary.

In the event of an infection on the foot, an antifungal powder should also be used. Consult a doctor or pharmacist for a recommendation for a specific preparation.

The symptoms of skin infection, such as itching or pain, should improve within a few days of treatment. However, signs such as redness and skin peeling may disappear after a longer period of time. If the symptoms persist, consult the doctor.

#### **Do not exceed the recommended dose.**

#### **For external use only.**

#### **Do not put the medicine into the mouth or swallow.**

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

**If you forget to use the medicine** at the required time, use the medicine as soon as possible and continue treatment as usual.

#### **How can you contribute to the success of the treatment?**

- Although the affected area will itch, avoid scratching it. Scratching will damage the surface of the skin and cause the infection to spread further.
- Keep the affected area clean.
- Moisture encourages fungal growth. Therefore, keep the affected area dry, but avoid excessive rubbing.
- Wash and dry the affected area before each application of the medicine. Between treatments - an antifungal powder can be used to keep the area dry.
- Always wash your hands after treating the infection, to avoid it from spreading.
- Do not share towels, bathmats and the like with others, as you could spread the infection to them.
- If the treatment is for the feet -
  - be sure to thoroughly wash and dry, especially between the toes.
  - it is recommended to use cotton socks; avoid wearing socks made of wool or synthetic materials. It is recommended to change them a few times a day (depending on the extent of perspiration).
  - thoroughly wash socks, nylon stockings and tights in hot water to remove any peeled skin or fungal spores.
  - in appropriate seasons, it is recommended to wear sandals without socks.
- 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 use of the medicine, consult the doctor or pharmacist.

### **4. SIDE EFFECTS:**

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

As with any medicine, some people may be allergic to the medicine. If you or your child are allergic, the reaction will develop immediately after commencing use. If you or your child are experiencing an allergic reaction, discontinue use and seek medical attention immediately. The signs of an allergic reaction can include: rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue, weakness, nausea, dizziness or fainting.

In addition, discontinue treatment and refer to a doctor if the following occur after use: redness, skin irritation or rash (rare), itching, blisters, burning, discomfort, swelling, skin peeling.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this 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](http://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>

In addition, you can report to the company via the following address: [www.perrigo-pharma.co.il](http://www.perrigo-pharma.co.il)

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

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach 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 tube. The expiry date refers to the last day of that month.
- Store below 25°C. After first opening can be used for 6 months.

### **6. FURTHER INFORMATION:**

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

Wool fat, kaolin, paraffin white soft, isopropyl myristate, zinc oxide, titanium dioxide, heavy liquid paraffin, dimethicone, squalane, propyl parahydroxybenzoate, butyl hydroxy toluene.

- What the medicine looks like and the contents of the package:

An aluminum tube, containing 30 grams of white/cream-colored paste.

#### **Manufacturer and registration holder:**

Padagis Israel Pharmaceuticals Ltd., P.O.B. 16, Yerucham.

Revised in October 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 14739.33586