

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

The medicine is dispensed without a doctor's prescription

# **AGISTEN BABY**

## **Paste**

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

Inactive and allergenic ingredients in the preparation - see in 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 the 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 fungal diaper rash in children, that lasts for more than 72 hours.

**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 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**

Before first use of this preparation, it is advisable to consult a doctor in order to avoid unnecessary use. This preparation should only be used in cases of irritation that have not passed after 72 hours.

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 Baby, tell the doctor if:**

- You are not sure if the patient suffers from 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.**

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

Agisten Baby 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 recommended dosage and instructions for use, unless instructed otherwise by a doctor: apply to the affected area twice a day, for 7-10 days.

Instructions for use:

Apply a thin and even layer of paste on clean, dry and aired skin and gently massage into the skin.

A quantity of a length of ½ cm of paste is enough to cover an area about the size of a palm.

It is recommended to change diapers frequently. It is preferable to leave the baby without a diaper as much as possible.

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 a 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 take 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.
- Wash your hands after treating the infection to avoid it from spreading.
- Do not share towels, bathmats and the like with the baby, since this can cause the infection to spread.

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 Baby 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, stop 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 you or your child experience one of the side effects mentioned above, if one of the side effects worsens or if you or your child 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 sight and 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 expiry date refers to the last day of that month.
- After first opening, can be used for 6 months.
- Store below 25°C.

### **6. FURTHER INFORMATION**

• In addition to the active ingredient, the medicine also contains:  
Wool fat, kaolin, paraffin white soft, isopropyl myristate, zinc oxide, heavy liquid paraffin, titanium dioxide, dimethicone, squalane, propyl parahydroxybenzoate, butyl hydroxy toluene (BHT).

• 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: 12594.26744.