

**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 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 the preparation in accordance with the instructions in the Dosage section in this leaflet. Consult the pharmacist if you need further information. Refer to the doctor if symptoms of the illness worsen or are not improving after 7 days.

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

For treatment of fungal nappy rash in children, that lasts over 72 hours.

**Therapeutic group:** Imidazole group antifungal.

### 2. BEFORE USING THE MEDICINE

#### Do not use the medicine:

- if you or your child is sensitive (allergic) to the active ingredient, or to any of the additional ingredients contained in the medicine.
- to treat infections on the scalp or nails.

### Special warnings regarding use of the medicine

Before first use of the preparation, it is advisable to consult a doctor to avoid unnecessary use. This medicine should only be used in cases of irritation that has 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 of the preparation with 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 is suffering from a fungal infection.
- the patient is sensitive to any food or medicine.

**If you or your child is taking, or has 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 and butylated hydroxytoluene, which may cause localized skin effects (e.g., contact dermatitis) or irritation of the eyes and mucous membranes. In addition, the medicine contains propyl paraben, which may cause allergic reactions (possibly delayed).

### 3. HOW SHOULD THE MEDICINE BE USED?

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

If the medicine was prescribed for you by the 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: spread twice a day on the affected area, for 7-10 days.

Instructions for use:

Spread a thin and even layer of the paste on clean, dry and aired skin and gently massage into the skin. A quantity of a length of ½ cm paste will be sufficient 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 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, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

**If you forgot to apply the medicine at the scheduled time,** apply 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.
- Keep the affected area clean.
- Dry the affected area thoroughly, but avoid excessive rubbing.
- Wash hands after treating the infection to avoid its spread.
- 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 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 Agisten Baby may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

As with any medicine, some people may be allergic to the medicine. If you or your child is allergic, the reaction will develop soon after commencing use of the preparation. If you or your child experiences an allergic reaction, **discontinue use and refer to a doctor immediately or proceed to the closest hospital emergency room.**

The signs of an allergic reaction may include:

rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue, weakness, nausea, dizziness or fainting.

After using the medicine, you may experience: itching, rash, blisters, burning sensation, discomfort, swelling, irritation, tingling, redness or skin peeling.

If a side effect occurs, if one of the side effects worsens, or if you or your child suffers 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](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, they can be reported to Padagis via the following address: [Padagis.co.il](http://Padagis.co.il)

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

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the sight and reach of children and/or infants 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 that contains 30 grams of an almost white paste.
- **Registration holder and manufacturer:** Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.
- Revised in July 2024 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 125-94-26744

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