Patient Package Insert in Accordance with the Pharmacists' Regulations (Preparations)-1986

This medicine can be sold without a physician's prescription

Agisten® Paste

Clotrimazole 1% W/W

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

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the physician or pharmacist.

Use the medicine in the correct manner. Consult the pharmacist if you need additional information. Contact a physician if the 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 chafing and skin infections caused by fungal strains sensitive to clotrimazole.

Therapeutic group: An antifungal product from the imidazole group.

2. Before using the medicine

Do not use the medicine:

- If you or your child are hypersensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains.
- for treatment of infections of the scalp or nails.

Special warnings regarding use of this medicine:

- Like other fatty products such as vaseline ointment, Agisten Paste may reduce the effectiveness of contraceptives made of rubber, such as a condom or diaphragm. Therefore, if the medicine is intended for use on the genitals, use an alternative method of contraception for at least five days after using this medicine.
- Do not use this medicine frequently or for a prolonged period without consulting a physician.
- Do not use on open wounds.
- Avoid contact of the product with the eyes and mouth. In case of contact with the eyes or mouth, wash thoroughly with water and refer to a physician.

Before treatment with Agisten Paste, tell the physician if:

- You are not sure if you (or your baby, in the case of diaper rash) suffer 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 physician or pharmacist.

Pregnancy and breastfeeding:

If you are pregnant, trying to conceive or breastfeeding, consult your physician or the medical staff before using the medicine.

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

Important information about some of the ingredients of this medicine

Agisten Paste contains butylated hydroxytoleune, wool fat, which may cause localized skin effects (e.g., contact dermatitis), or irritation of the eyes and mucus membranes.

3. How to use the medicine

Check with the physician or pharmacist if you are uncertain.

If the medicine was prescribed for you by the physician, follow his/her instructions.

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

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

Instructions for use:

Evenly apply a thin layer of paste on clean, dry and aired skin and gently massage into the skin. A small quantity the length of ½ cm of paste is usually enough to cover an area the size of a palm.

The duration of treatment depends on the type of infection. In general, it is necessary to use it for a period of at least two weeks, although a treatment period of 4 weeks may be necessary.

In case of a foot infection, it is advisable to also use an antifungal powder. Consult a physician or pharmacist for a recommendation for a particular product.

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 physician.

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 physician 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.
- 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 - you can use antifungal powder to keep the area dry.
- Always wash your hands after treating the infection to avoid it spreading.
- Do not share towels, bathmats and the like with other people, since the infection may spread to them.
- If the treatment is on the feet –
  - Be sure to thoroughly wash and dry, especially between the toes.
  - It is advisable to use cotton socks; avoid wearing socks made of wool or synthetic materials. It is advisable to change them several times a day (according to the amount of sweat).
  - Thoroughly wash your socks, nylon socks and pantyhose in hot water to remove all of the flaked skin or fungal spores.
  - In the 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 any further questions about the use of the medicine, ask your physician or pharmacist.

4. Side effects

Like with all medicines, the 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 all medicines, some patients 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 physician if the following occur after use: redness, skin irritation or rash (rare), itching, blisters, burning, discomfort, swelling, peeling of skin.

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, you should consult the physician

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report side effects due to 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

In addition, you can report to the company via the following address: Padagis.co.il

5. How to store the medicine

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed 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 physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package/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. Additional 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 parahydroxy benzoate, butyl hydroxy toluene.

- What the medicine looks like and the contents of the package:
  An aluminum tube containing 30 grams of almost white-colored paste.

Manufacturer and registration holder: Padagis Israel Pharmaceuticals Ltd., 1 Rakefet Street, Shoham.

Revised in November 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 147-39-33586

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