

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 in 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 medicine properly. Consult a pharmacist if you need further information. Refer to the doctor if the symptoms of the illness worsen or are not improving after 7 days.

1. WHAT IS THIS MEDICINE INTENDED FOR?

For treatment of abrasions and skin infections caused by fungal strains sensitive to clotrimazole.

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:

- As with other preparations, Agisten Paste may reduce the effectiveness of rubber contraceptives, such as a condom or diaphragm. Therefore, if the medicine is intended for use on the genitals, use alternative contraceptives 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 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 Paste, tell the doctor if:

- you are not sure that you or your child 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.

Pregnancy, breastfeeding and fertility

Pregnancy and breastfeeding:

If you are pregnant, are trying to become pregnant or are breastfeeding, consult a doctor or pharmacist before using the preparation and follow his/her instructions. This preparation can be used during pregnancy only under the supervision of a doctor.

This preparation can be used while breastfeeding, but rinse the nipple area before breastfeeding if this preparation is used in the nipple area.

Fertility:

There are no data indicating fertility problems associated with use of the preparation.

Driving and operating machinery

Agisten Paste has no or only a negligible effect on ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

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

In addition, the preparation contains propyl paraben, which may cause allergic reactions (late responses are possible).

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 preparation.

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 instructions below:

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

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 small quantity of a length of ½ cm paste will generally be sufficient to cover an area the size of the palm.

Treatment duration depends on the type of infection. In general, it must be used for a period of at least two weeks, but a treatment period of 4 weeks may be necessary.

In case of an infection on the foot, it is advisable to also use an antifungal powder. 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 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 well, but avoid excessive rubbing.
- Moisture promotes 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.
- Do not share towels, bathmats and the like with other people, since the infection may spread to them.
- Take care to always wash hands after treatment of the infection to avoid it from spreading.
- If the treatment is on the legs –
 - Be sure to thoroughly dry the skin, especially between the toes.
 - Thoroughly wash socks, nylon stockings and tights in hot water to remove the skin that has peeled off or the fungal spores.
 - If possible, change shoes every day.

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 Paste 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.

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

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

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 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> In addition, they can be reported to the company via the following address: 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 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/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, squalene, propyl parahydroxy benzoate, butylhydroxytoluene.

• 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: 147-39-33586

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