

Patient Package Insert According to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold without a physician's prescription

Agisten® Solution

Clotrimazole 1% W/W

Inactive ingredients and allergens in the medicine – see section 2 “Important information about some of the ingredients of this medicine” and section 6 “Additional information” of the leaflet.

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine.

If you have any further questions, ask your doctor or pharmacist. Use this medicine according to the instructions in section 3 “How to use this medicine?” of this leaflet.

Consult a pharmacist if you need more information.

You should refer to the doctor if the signs of illness (symptoms) worsen or do not improve after 4 weeks.

1. WHAT IS THE MEDICINE INTENDED FOR?

Skin infection caused by dermatophytes or candida species.

Therapeutic group: An antifungal medicine for external use from the imidazole or triazole group.

Agisten Solution is intended to treat fungus and jock itch. The medicine treats a variety of fungal strains, which may appear in different areas of the body: the feet and toes, armpits, groin, skin folds and other areas of the skin.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are hypersensitive (allergic) to the active ingredient clotrimazole or to any of the other ingredients this medicine contains (see section 6 “Additional information” of the leaflet).

Special warnings regarding the use of this medicine

Warning! Inflammable, keep away from fire. Do not light a cigarette or be exposed to fire until the product has completely dried.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription drugs and nutrition supplements, tell the doctor or pharmacist.

Pregnancy and breastfeeding

If you are pregnant, breastfeeding or are trying to become pregnant, consult the doctor or the medical staff before using the medicine. Agisten Solution can be used during pregnancy and breastfeeding. If you consulted the doctor, carefully follow the instructions of the doctor and the medical staff. If the medicine is used on the breast area, wash the area well before breastfeeding.

Important information about some of the ingredients of this medicine

The medicine contains propylene glycol, which may cause skin irritation. Do not use the medicine in babies under 4 weeks of age, on open wounds or on large areas of damaged skin (such as after burns) without consulting the doctor or the pharmacist.

3. HOW TO USE THIS MEDICINE?

Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

The usual recommended dosage is: treatment twice a day (morning and evening).

If the medicine has been prescribed for you by the doctor, follow his/her instructions.

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

Duration of treatment:

The average duration of treatment for various fungal skin infections ranges from 2 to 3 weeks.

If there is no improvement in your condition within 4 weeks, refer to a doctor.

Do not exceed the recommended dose.

How to use:

For external use only.

- Clean and dry the affected area.
- Apply a small amount of Agisten Solution to the affected area and massage it into the skin.
- Usually, a few drops will suffice to cover an area the size of a palm.
- Agisten Solution is suitable for use on hairy skin.
- Agisten Solution can be washed off with water and does not stain.
- In order to prevent the recurrence of fungal infections (especially on the feet), the treatment should be continued for approximately two weeks after the disappearance of all signs of fungal infection.
- In case of athlete's foot, it is recommended to also use anti-fungal powder. Consult a doctor or pharmacist about a recommended medicine.

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

Do not put the solution in your mouth or swallow it.

Avoid contact of the medicine with mucous membranes (such as eyes, mouth and nose).

If the medicine accidentally comes into contact with the mouth or eyes, immediately rinse thoroughly with water and refer to a doctor.

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

If you forgot to use this medicine at the set time, use the medicine as soon as possible and continue treatment as usual. Even if there is an improvement in your health, do not stop the treatment with this medicine without consulting the doctor or pharmacist.

You can help the success of the treatments if you follow the following tips:

- Although the infected area will itch, try not to scratch. Scratching will damage the surface of the skin and cause the infection to spread further.
- Keep the affected skin areas clean.
- Keep the affected area dry, but avoid excessive rubbing.
- Do not share towels, bath mats, etc. with other people as you could spread the infection to them.
- Always wash your hands after treating the infection to prevent it from spreading.
- If the treatment is for the feet:
 - Be sure to thoroughly wash and dry, especially between the toes.
 - Wash your socks, nylon stockings and tights thoroughly in hot water to remove any shed skin or fungal spores.
 - Change your footwear daily if possible.

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, the use of Agisten Solution may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

As with all medicines, there are people who may be allergic to the solution. If you are allergic, a reaction will develop immediately after you start using it. If you experience an allergic reaction, **stop using it and refer to a doctor immediately.**

Signs of an allergic reaction can include:

- rash.
- swallowing or breathing problems.
- swelling of the lips, face, throat or tongue.
- weakness, feeling dizzy or faint.
- nausea.

After you apply the solution, you might experience:

itching, rash, blisters, burning, discomfort, swelling, irritation, pins and needles, redness or peeling of the skin.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting of 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 home page of the Ministry of Health website (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>

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

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight 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.
- Store below 25°C.
- After the first opening, can be used for 60 days, but no later than the expiry date.
- Caution! Inflammable, keep away from fire.

6. ADDITIONAL INFORMATION

- **In addition to the active ingredient, the medicine also contains:**
Propylene Glycol, Isopropanol, Polyethylene Glycol 400
- **What the medicine looks like and contents of the package:**
A plastic bottle containing 20 ml of transparent to yellowish liquid.
- **Registration Holder and Manufacturer:** Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.
- Revised in November 2024 according to MOH guidelines.
- **Drug registration number in the National Drug Registry of the Ministry of Health:** 042-26-22463.
- Agisten is a registered trademark of Padagis Israel Pharmaceuticals Ltd.