

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

This medicine can be sold without a physician's prescription

Agisten® Cream

Active ingredient:

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".

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

Use this medicine according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you need additional information. Contact a physician if the symptoms of your illness get worse or if they do not improve after 4 weeks.

1. What is the medicine intended for?

Agisten Cream is used to treat skin and mucous tissue infections caused by various types of fungi. It is also used to treat candida infections of the vulva and of the penis.

Therapeutic group: Antifungal agents for local use of the Imidazole group.

2. Before using the medicine

Do not use the medicine:

- If you are hypersensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains, including cetostearyl alcohol (see section 2 "Important information about some of the ingredients of this medicine" and section 6 "Additional information").
- To treat fungus on your nails or on the scalp.

Special warnings regarding the use of the medicine:

As with other creams, Agisten Cream may lower the effectiveness of contraceptives made of rubber, such as a condom or diaphragm. Therefore, if you are using Agisten Cream on the vulva or penis, use alternative contraceptives for at least five days after the use of this medicine.

If your condition does not improve within 4 weeks, refer to the doctor.

Drug interactions:

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

Pregnancy, breastfeeding and fertility:

If you are pregnant, breastfeeding or trying to become pregnant, consult the physician or pharmacist before using the medicine.

Driving and using machines:

Agisten Cream has no effect on the ability to drive or use machines or has only a negligible effect.

Important information about some of the ingredients of this medicine:

Agisten Cream contains Cetostearyl Alcohol which may cause local skin irritation (e.g., rash, itching or redness).

Agisten Cream contains 10 mg of Benzyl Alcohol per 1 gram of cream which may cause an allergic reaction.

3. How to use the medicine

Check with the physician or pharmacist if you are not sure about the dosage and treatment regimen.

If the medicine is prescribed to you by a physician follow his instructions.

If you purchased this medicine without a physician's prescription, use the medicine according to the instructions in this section.

The usual recommended dosage is: treatment 2 to 3 times a day.

How to use:

- Opening instructions – to open the tube turn the cap over and pierce the tube seal by pressing the cap.
- For the treatment of foot fungus: Thoroughly wash and dry the feet, especially between the toes, before applying the cream.
- Apply a thin and even layer on the affected areas 2 to 3 times a day and massage the cream into the skin.
- Usually a small amount of ½ cm of cream will suffice to treat an area the size of a palm.
- The duration of treatment for fungal skin infections depends on the type of infection. Usually, the duration of treatment will be at least two weeks, although up to 4 weeks of treatment may be necessary.
- If you have foot fungus, it is advisable to also use an antifungal powder. Consult the physician or pharmacist.
- Symptoms of skin infection, such as itching and pain, are expected to improve within a few days of starting treatment, but symptoms such as redness and skin peeling may take longer to disappear.
- If your condition does not improve within 4 weeks, consult the physician.

Do not exceed the recommended dose.

For external use only.

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

• If you accidentally swallowed the medicine, proceed immediately to the physician or to the closest hospital emergency room.

• Avoid contact of the medicine with the eyes or mouth. In case of contact with the eyes, wash thoroughly with water and refer to the doctor.

• **If you have accidentally taken a higher dosage**, if you took an overdose or if a child or someone else has accidentally swallowed the medicine, proceed immediately to the physician or to a hospital emergency room and bring the medicine package with you.

• **If you forgot to apply the medicine at the required time**

- Apply it immediately when you remember and continue the rest of the treatment as usual.

• **How can you contribute to the success of the treatment?**

- Although the affected area is itchy, avoid scratching it. Scratching may damage the surface of the skin and thus cause the infection to spread.
- Keep the affected areas clean.
- Thoroughly dry the area but avoid excessive rubbing.
- Do not share towels, bath mats, etc. with others as the infection may spread to them.
- Be careful to wash your hands after every treatment of the infection to prevent its spread.

• If you have foot fungus:

- Be careful to thoroughly dry the skin between the toes.
- Thoroughly wash the socks and tights in warm water to remove shed skin or fungal spores.
- Change shoes daily if possible.

• **Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

• **If you have further questions on the use of this medicine, consult the physician or pharmacist.**

4. Side effects

As with any medicine, the use of Agisten Cream 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, there are people who may be hypersensitive (allergic) to this cream. If you are allergic, the reaction will develop soon after using the medicine.

Stop the treatment and proceed immediately to the physician or the nearest hospital emergency room if an allergic reaction develops. Signs of an allergic reaction may 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 one of the following symptoms: itching, rash, blisters, burning, discomfort, swelling, irritation, redness or peeling of the skin.

If a side effect appears, if one side effect gets worse or if you suffer from a side effect which is not mentioned in this leaflet, consult the physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects from Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or by clicking on the following link: <https://sideeffects.health.gov.il>

Additionally, side effects can be reported to Padagis via the following address: www.perrigo-pharma.co.il

5. How to store the medicine

• Avoid poisoning! This medicine and any other medicine 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 physician.

• 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.

Storage conditions:

- Store in a cool place below 25°C.
- After first opening, the medicine can be used for 6 months, and not later than the expiry date that appears on the package.

6. Additional information

• **In addition to the active ingredient, Agisten Cream also contains:**

Octyldodecanol, Cetostearyl Alcohol, Cetyl Esters Wax, Sorbitan Monostearate, Polysorbate 60, Benzyl Alcohol, Purified Water

• **What does the medicine look like and what is the contents of the package:**

Agisten Cream is a white cream packaged in an aluminum tube that contains 30 grams.

• **Manufacturer and registration holder:** Padagis Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.

• Revised in September 2021 according to MOH guidelines.

• **Registration number of the medicine at the National Drug Registry of the Ministry of Health:** 130-70-30920