

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed without a doctor's prescription

Agisten V® 0.2 g Vaginal Tablets

Vaginal tablets (for intravaginal use)

Clotrimazole 200 mg

Inactive and allergenic ingredients in the preparation – see section 6 "Further information" in the leaflet.

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 according to the instructions in the dosage section of this leaflet. Consult a 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 THE MEDICINE INTENDED FOR?

Agisten V 0.2 g Vaginal Tablets is a preparation for the treatment of infections in external female genital organs and vagina caused by clotrimazole-sensitive microorganisms such as fungi (as *Candida albicans*) in adults and children 12 years of age and older.

Vaginal thrush is a common infection most women suffer from at some stage in their lives, and is not caused by poor personal hygiene. The cause of vaginal thrush is a fungus called *Candida*, which lives harmlessly in the vagina and other organs unnoticed.

However, the natural balance that keeps *Candida* under control can be affected by several factors, such as hormonal changes (menstrual cycle, oral contraceptives, pregnancy, menopause), poor health, use of antibiotics, scented soaps, bath additives and tight-fitting clothes.

A change in the natural pH balance may lead to an increase in fungal growth, which can then develop into thrush. This can manifest by the following symptoms: persistent burning sensation and/or itch around the vagina and vulva, redness, swelling and pain in the vaginal and vulval tissues and white, odorless vaginal discharge. You may not suffer from all the symptoms listed, but only from one of them.

2. BEFORE USING THE MEDICINE

Do not use Agisten V 0.2 g Vaginal Tablets if:

you are sensitive (allergic) to the active ingredient (clotrimazole) or to any of the additional ingredients contained in the medicine (see section 6 "Further information").

Special warnings regarding use of Agisten V 0.2 g Vaginal Tablets

• **Only use the preparation if a doctor has previously diagnosed you with vaginal thrush.**

Before treatment with Agisten V 0.2 g Vaginal Tablets, tell the doctor if:

- You are not sure that you are suffering from vaginal thrush or this is the first time you are suffering from these symptoms.
- You suffered from more than two vaginal infections in the last 6 months.
- You or your partner has ever suffered from a sexually transmitted disease.
- You are under the age of 16 years or over the age of 60 years.
- You have ever had an allergic reaction to Agisten V 0.2 g Vaginal Tablets or to other vaginal antifungal preparations.
- If one of the following symptoms occurs, Agisten V 0.2 g Vaginal Tablets may not be the right treatment for you:
 - irregular vaginal bleeding.
 - abnormal vaginal bleeding or bloody discharge.
 - vaginal or vulval ulcers, blisters or sores.
 - lower abdominal pain.
 - pain or difficulty in urination.
 - fever or chills.
 - nausea or vomiting.
 - diarrhea.
 - a foul-smelling vaginal discharge.
- Agisten V 0.2 g Vaginal Tablets, like other preparations for intravaginal use, may reduce the effectiveness of rubber contraceptives, such as a condom or diaphragm. Therefore, use alternative contraceptives for at least 5 days after treatment with the preparation.
- Do not use tampons, intravaginal douches, spermicides or other vaginal preparations during the course of treatment with this medicine.
- Avoid vaginal intercourse when suffering from thrush and while using Agisten V 0.2 g Vaginal Tablets, since your partner may become infected.

Girls and female adolescents

Agisten V 0.2 g Vaginal Tablets is intended for use by girls and female adolescents from the age of 12 years and above.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

- tacrolimus or sirolimus (intended to reduce the immune reaction to prevent implant rejection after organ transplantation).

Pregnancy, breastfeeding and fertility

Fertility

No studies of the effect of the medicine on human fertility have been conducted. However, studies in animals have not shown any effect on fertility.

Pregnancy

If you are pregnant, trying to become pregnant, or are breastfeeding, tell the doctor or pharmacist before using Agisten V 0.2 g Vaginal Tablets and follow their instructions carefully. Clotrimazole can be used during pregnancy, but under medical supervision only. Do not use an applicator throughout pregnancy.

Breastfeeding

There is no data regarding passage of the medicine into breast milk. Since absorption into the circulation after use of the preparation is negligible, it is unlikely to lead to systemic effects. The preparation can be used when breastfeeding.

Driving and operating machinery

This medicine has no or a negligible effect on ability to drive or operate machinery.

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.

The recommended dosage is usually:

One tablet to be inserted into the vagina at bedtime, on 3 consecutive nights (see under "How to use the preparation – general instructions").

Do not exceed the recommended dose.

Duration of treatment:

- The symptoms of thrush should pass within 3 days from the start of treatment. If there is no improvement within 7 days, refer to a doctor.
- If the thrush is reoccurring after 7 days, one additional treatment can be used. However, if you suffer from thrush more than twice within 6 months, refer to a doctor.

Mode of administration:

- **Do not put in the mouth or swallow!**
- **For intravaginal use only.**

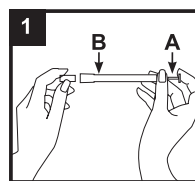
How to use the preparation – general instructions:

If Agisten V 0.2 g Vaginal Tablets was prescribed for you by your doctor, follow his/her instructions.

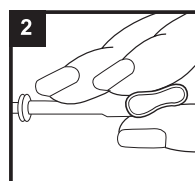
If you purchased the preparation without a doctor's prescription, use it as described in this section. The applicator provided with the preparation is intended to help insert the tablet as deeply as possible into the vagina, preferably at bedtime, for **three consecutive nights.**

Wash your hands before removing the tablet from the package and again after using the special applicator. If you are pregnant, do not use the applicator to insert the medicine.

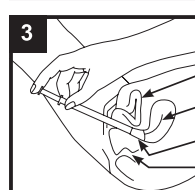
1. Remove the applicator from the box. Pull out the plunger (A) until it stops. Remove the vaginal tablet from the aluminum blister and place it firmly into the wide end of the applicator (B).



2. To fit the tablet into the applicator, the applicator end needs to be lightly squeezed on both sides. The tablet fits tightly into the applicator and should be pressed up to a depth of 1 cm.



3. Insert the applicator containing the tablet into the vagina as deeply as possible so long as it does not cause discomfort (the best way to do this is while lying on your back with legs bent and your knees facing upwards). Hold the applicator in place and slowly press the plunger until it stops, so that the tablet is inserted into the vagina.



4. Remove the applicator. After use, completely remove the plunger (A) from the applicator (B). Wash all parts with warm (not boiling) water and soap for 30 seconds, and dry carefully. Until next use, keep all the parts in a clean and safe place.
5. After completing treatment, dispose of the applicator in a safe place, out of the reach and sight of children. Do not dispose the applicator in the toilet.

• The intravaginal tablet dissolves in the vagina; therefore, it is recommended to use a panty liner, as white residue is frequently seen after using the preparation. This does not indicate that the treatment did not work properly. However, if you notice whole pieces of the tablet that did not dissolve, the treatment may not have been successful and you should refer to a doctor or pharmacist.

• To prevent future recurrence: only wear cotton underwear that is not too tight, shower every day, wiping in the bathroom should be done from front to back, as a vaginal infection can be transmitted from the bowels. Replace sanitary protectors frequently, avoid wearing clothing that is too tight and nylon stockings, avoid washing with perfumed soaps or using deodorants in the vaginal area, do not rub the area firmly with a wash sponge, avoid hot baths with strong scented oils.

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

If you forgot to use this medicine at the scheduled time

- Use the dose as soon as you remember and continue with the rest of treatment as usual.
- If you forgot for more than one day, the vaginal infection may not have been fully treated. Therefore, if the symptoms persist after completion of treatment, refer to a doctor.

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 V 0.2 g Vaginal Tablets may cause side effects in some users. Do not be alarmed when reading the side effects. You may not suffer from any of them.

As with any medicine, some people may be allergic to it. If you suffer from a sensitivity (allergy) to the preparation, an allergic reaction will occur soon after using the preparation. **Stop the treatment and refer immediately to a doctor or proceed to the closest emergency room** if you develop an allergic reaction or worsening redness, burning sensation, pain, itch or worsened swelling. Signs indicative of an allergic reaction include: rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue, weakness, dizziness or fainting, nausea.

Effects that may occur after using the intravaginal tablet:

- itching, rash, swelling, redness, discomfort, burning sensation, irritation, vaginal peeling, vaginal discharge or vaginal bleeding.
- pain (e.g., in the abdomen, in the pelvic area).
- nausea.

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 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, it can be reported to Padagis 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 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 in a cool place below 25°C.
- Do not discard medicines in the wastewater or household waste. Consult a pharmacist how to dispose of medicines that are no longer needed. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: Lactose Monohydrate 200, Microcrystalline Cellulose, Maize Starch, Poly (1-vinyl-2-pyrrolidone) (Crospovidone), Lactic Acid, Magnesium Stearate, Calcium Lactate, Colloidal Silicon Dioxide (Aerosil 200), Hydroxypropyl Methylcellulose Hypromellose.

What the medicine looks like and the contents of the package: Agisten V 0.2 g Vaginal Tablets package contains 3 nearly white to slightly yellowish vaginal tablets, packaged in an aluminum blister, and one applicator (for insertion of the tablet into the vagina).

• **Manufacturer, registration holder and address:** Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.

• Revised in March 2025 according to MOH guidelines.

• **Registration number of the medicine in the National Drug Registry of the Ministry of Health:**

026-13-25080/140-29-31940

Agisten V® is a trademark of Padagis Israel Agencies Ltd.