

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

The medicine is dispensed without a doctor's prescription.

## Agisten V® 0.5 gram Vaginal Tablet

Each vaginal tablet contains:

**Clotrimazole 500 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?

A broad-spectrum antimycotic medicine that kills fungi and trichomonas, for one-time topical treatment of vaginal infections.

**Therapeutic group:** The active ingredient clotrimazole belongs to the azole group and is an antifungal agent that fights the cause of infections such as vaginal infections.

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 parts of the body without you even noticing it.

However, the natural balance that keeps Candida under control can be influenced by several factors, such as: hormonal changes (menstrual cycle, oral contraceptives, pregnancy, menopause), poor health, use of antibiotics, scented soaps, bath supplements and tight-fitting clothes. A change in the natural pH balance may lead to an increase in fungal growth that may 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 detailed, but only from one of them.

### 2. BEFORE USING THE MEDICINE

**Do not use the medicine:**

- if you are sensitive (allergic) to the active ingredient clotrimazole or to any of the additional ingredients contained in the medicine.
- during your period as it may be less effective.

**Special warnings regarding use of the preparation Before treatment with Agisten V 0.5 gram, tell the doctor if:**

- you suffered from more than two vaginal fungal infections in the last 6 months.
- you or your partner has ever suffered from a sexually transmitted disease.
- you are not sure that you are suffering from vaginal thrush or if this is the first time you are suffering from these symptoms.
- you are under the age of 16 years or over the age of 60 years.
- you are pregnant or suspect you are pregnant.
- you have ever had an allergic reaction to Agisten V 0.5 gram or to other vaginal antifungal preparations.
- you have one of the following symptoms:
  - irregular vaginal bleeding.
  - abnormal vaginal bleeding or bloody vaginal discharge.
  - vaginal or vulval ulcers, blisters or sores.
  - lower abdominal pain.
  - pain or difficulty in passing urine.
  - fever or chills.
  - feeling nauseous or vomiting.
  - diarrhea.
  - a foul-smelling vaginal discharge.

This is because treatment with Agisten V 0.5 gram is not the right treatment for you.

- As with other preparations for intravaginal use, this preparation may reduce the effectiveness of rubber contraceptives, such as condoms or diaphragms. Therefore, use alternative contraceptives for at least 5 days after using the preparation.
- Do not use tampons, intravaginal douches, spermicides or other vaginal preparations during the course of treatment.
- Avoid intercourse when suffering from thrush and during the course of treatment, since your partner may become infected.

### Girls and female adolescents:

Agisten V 0.5 gram is not intended for use by girls and female adolescents under 12 years of age.

### Drug interactions:

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist before you commence treatment.** Especially if you are taking:

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

### Pregnancy, breastfeeding and fertility:

Agisten V 0.5 gram can be used during pregnancy and when breastfeeding.

If you are pregnant, breastfeeding, or trying to become pregnant, tell the doctor before using Agisten V 0.5 gram. If you already told the doctor, follow his/her instructions carefully.

For treatment of internal thrush, the doctor may recommend treatment with tablets, without use of an applicator.

### Driving and operating machinery:

This medicine does not affect driving and/or use of 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:

1 tablet to be inserted into the vagina with an applicator at bedtime.

### Do not exceed the recommended dosage.

- The symptoms of thrush should pass in 3 days of treatment. If there is no improvement after 7 days, inform the doctor.
- If the infection recurs after 7 days, one additional treatment can be used. But if you have already had an infection twice in the last 6 months, refer to the doctor.

**This medicine is intended for intravaginal use only. Do not put in the mouth or swallow.**

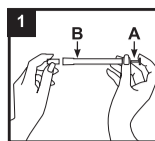
### How to use:

If Agisten V 0.5 gram was prescribed for you by a doctor, follow his/her instructions. If you purchased the preparation without a doctor's prescription, follow the following instructions:

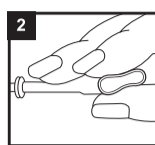
Use the applicator to insert the tablet as deeply as possible into the vagina, preferably at bedtime, for treatment convenience.

Wash your hands before removing the tablet from the package and again after using the applicator.

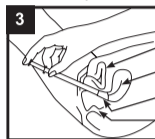
1. Remove the applicator from the package. Pull out the plunger (A) until it stops. Remove the vaginal tablet from the aluminum blister pack and place it firmly into the wide end of the applicator (B).



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



3. Carefully insert the applicator as deep as is comfortable into the vagina (the easiest way to do this is while lying on your back with your knees bent upwards). Hold the applicator in place and slowly press the plunger until it stops so that the tablet is placed in the vagina.



4. Remove the applicator. Dispose of the applicator in a safe place; keep out of the reach of children. Do not dispose of the applicator in the toilet.

- Since the tablet dissolves in the vagina, it is recommended to use a panty liner, as it is quite common to see white discharge after using the vaginal tablets. This does not indicate that the treatment did not work. However, if you notice pieces of the tablet that did not dissolve, refer to a doctor or pharmacist as it may be that the treatment did not work properly.

- To prevent future recurrence: wear cotton underwear that is not 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 panty liner regularly. Avoid wearing nylon underwear and tight jeans. Avoid washing with perfumed soaps or using deodorants in the vaginal area. Do not rub the area strongly with a wash sponge. Avoid hot baths with scented oils.

If you accidentally used a higher dosage, 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.

**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 0.5 gram 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 people may be allergic to the vaginal tablets. If you are allergic, an allergic reaction will develop soon after using the preparation. **Stop using the preparation and refer immediately to a doctor** or proceed to the closest emergency room if you experience an allergic reaction or worsening redness, burning, pain, itch or swelling.

Signs of an allergic reaction can include:

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

After using Agisten V 0.5 gram Vaginal Tablets, you may experience:

- itching, rash, swelling, redness, discomfort, burning, irritation, vaginal peeling, discharge or bleeding.
- pains in the abdomen or 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 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](http://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 Padagis via the following address: [Padagis.co.il](http://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 carton package. The expiry date refers to the last day of that month. Do not discard medicines in the wastewater or household waste. Ask the pharmacist how to dispose of medicines that you no longer need. These measures will help protect the environment.
- Store in a cool place below 25°C.

### 6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Lactose monohydrate, Microcrystalline cellulose, Lactic acid, Maize starch, Crospovidone, Calcium lactate, Magnesium stearate, Colloidal anhydrous silica, Hydroxypropyl methylcellulose.

What the medicine looks like and the contents of the package:

Agisten V 0.5 gram Vaginal Tablet package contains: one white-yellow tablet, packaged in an aluminum blister, and one applicator.

- 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: 031-74-25210

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