

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

This medicine can be sold without a physician's prescription.

Agisten® V 0.2 g Vaginal Tablets

Vaginal tablets (for intravaginal use)

Clotrimazole 200 mg

Inactive ingredients and allergens in the product - see section 6 "Additional information" in this leaflet.

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 product 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 the illness get worse or if they do not improve after 7 days.

1. What is the medicine intended for?

Agisten V 0.2 g Vaginal Tablets are intended to treat vaginal thrush that is caused primarily by candida strains.

To treat vaginal infections caused by trichomonas and microorganisms sensitive to clotrimazole.

Therapeutic group: Antifungals of the azole group.

Vaginal thrush is a common infection that most women suffer from at some point in their lives and is not caused by poor personal hygiene. The cause of vaginal thrush is a fungus called candida that lives in the vagina and other organs without causing any damage.

However, the natural balance that keeps candida under control can be affected by several factors such as hormonal changes (menstruation, contraceptive pills, pregnancy, menopause), poor health, taking antibiotics, perfumed soaps, bath additions and tight clothing. A change in the natural acidity balance (pH) may lead to an increase in the growth of the fungus that can then develop into an infection. This can be manifested by the following symptoms: persistent burning sensation and/or itching around the vagina and vulva, redness, swelling and pain of the vaginal and vulval tissues and a white, odorless vaginal discharge. You may not have all these symptoms, but only have one of them.

2. Before using the medicine

Do not use Agisten V 0.2 g Vaginal Tablets 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").

Special warnings regarding the use of Agisten V 0.2 g Vaginal Tablets:

• **Use this product only if a doctor has previously diagnosed you with vaginal thrush.**

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

- You are not sure if you have vaginal thrush or if this is the first time you have these symptoms.
- You have had more than two vaginal thrush infections during the last 6 months.
- You or your partner have ever had a sexually transmitted disease.
- You are under 16 years of age or over 60 years of age.
- You have ever had an allergic reaction to Agisten V 0.2 g Vaginal Tablets or to other vaginal antifungal products.
- If any of the following symptoms appear, 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.
 - Difficulty or pain when passing urine.
 - Fever or chills.
 - Nausea or vomiting.
 - Diarrhea.
 - Foul-smelling vaginal discharge.

- Agisten V 0.2 g Vaginal Tablets, like other products for intravaginal use, may reduce the efficacy of contraceptives made of rubber, such as a condom and a diaphragm. Therefore, you should use alternative contraceptives for at least 5 days after treatment with this product.
- Do not use tampons, vaginal douches, spermicides or other vaginal products during the course of treatment with this product.
- Avoid vaginal intercourse as long as you have a vaginal thrush or during use of Agisten V 0.2 g Vaginal Tablets, as your partner may get infected.

Girls and adolescent girls:

Agisten V 0.2 g Vaginal Tablets are not intended for use in girls and adolescents under the age of 12 years.

Drug interactions:

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

- Tacrolimus or sirolimus (intended to reduce the immune system response in order to prevent graft rejection after an organ transplant).

Fertility, pregnancy and breastfeeding: Fertility

There is information showing that the product has no effect on fertility.

Pregnancy

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

Breastfeeding

As a risk to the breastfeeding infant cannot be ruled out, it should be decided together with the physician whether to breastfeed or to use clotrimazole.

Driving and using machines:

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

3. How to use the medicine

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

The usual recommended dosage is:

One tablet for intravaginal insertion in the evening before sleep for 3 consecutive evenings (see section "How to use".)

Do not exceed the recommended dose.

Treatment duration:

- The signs of thrush should disappear within 3 days from the beginning of treatment. If there is no improvement in your condition after 7 days, contact a physician.
- If the thrush returns after 7 days, you can use an additional treatment, but if you have more than two infections in 6 months, you should contact a physician.

Method of administration:

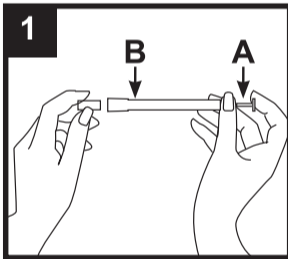
- **Do not put in mouth or swallow!**
- **For intravaginal use only.**

How to use the product – general instructions:

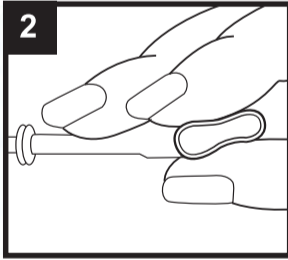
If Agisten V 0.2 g Vaginal Tablets are prescribed for you by your physician, follow his instructions. If you purchased the product without a physician's prescription, use the product as described in this section. The applicator supplied with the product is intended to assist in inserting the tablet as deeply as possible into the vagina, preferably before going to sleep for **three consecutive evenings**.

Wash your hands with soap and hot water before removing the tablet from the package and again after using the special applicator. If you are pregnant, check with the physician whether to use the applicator to insert the tablet.

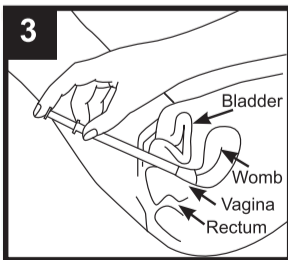
1. Remove the applicator from the package. Pull out the plunger (A) until it stops. Remove the vaginal tablet from the aluminum blister and place it in the wide end of the applicator (B).



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



3. Insert the applicator containing the tablet into the vagina as deeply as possible without causing discomfort, (the best way to do this is while lying on your back with bent legs, and with your knees pointing upward). 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 with warm water (not boiling) and soap, and dry carefully.
5. After completing treatment, dispose of the applicator in a safe place, out of the reach of children. Do not dispose of the applicator in the toilet.

• The intravaginal tablet dissolves in the vagina, therefore, it is recommended to wear a panty liner as it is quite common to notice white residues after using the product. This does not indicate that the treatment has not worked properly. If you notice whole pieces of undissolved tablet fragments, the treatment may

not have succeeded, and you should contact the physician or pharmacist.

- To prevent future recurrence: wear only cotton underwear that is not too tight, and change it frequently. Shower each day. Wiping yourself in the toilet should be done from front to back. Avoid wearing clothing that is too tight and nylon stockings. Avoid washing yourself with perfumed soaps or using deodorants in the area of the vagina. Do not rub the area firmly with a wash sponge. Avoid hot baths with perfumed oils.

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

If you forgot to use the product at the designated time

- Use the dose as soon as you remember and continue the rest of the treatment as usual.
- If you forgot for more than one day, your vaginal infection may not be fully treated. Therefore, if the symptoms continue after completing the treatment, you should contact the physician.

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 V 0.2 g Vaginal Tablets 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.

If you are sensitive (allergic) to the product, an allergic reaction will occur soon after using the product. **Stop using the product and proceed immediately to a physician or a nearby hospital emergency room** if you experience an allergic reaction or worsening of redness, burning sensation, pain, itching or worsened swelling.

Signs that indicate an allergic reaction include: rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue, weakness, dizziness or fainting, nausea.

Side effects that may appear after using the intravaginal tablet:

- Itching, redness, rash, swelling, discomfort, burning, irritation, vaginal peeling or bleeding.
- Pain in the stomach or pelvic area.

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.

Reporting of side effects:

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: Padagis.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 carton. The expiry date refers to the last day of that month.
- Store in a cool place below 25°C.
- Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. Additional information

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

Lactose Monohydrate 200, Microcrystalline Cellulose, Maize Starch, Poly (1-vinyl-2-Pyrrolidone) (Crosopovidone), Lactic Acid, Magnesium Stearate, Calcium Lactate, Colloidal Silicon Dioxide (Aerosil 200), Hydroxypropyl Methylcellulose Hypromellose.

• **What does Agisten V 0.2 g Vaginal Tablets look like and what is the content of the package:**

The package of Agisten V 0.2 g Vaginal Tablets contains 3 almost white to yellowish vaginal tablets packaged in an aluminum blister and one applicator (for the insertion of the tablet into the vagina).

- **Manufacturer and registration holder:** Padagis Israel Pharmaceuticals Ltd., 1 Rakefet st., Shoham.
- Revised in November 2022 according to MOH guidelines.
- **Registration number of the medicine at the National Drug Registry of the Ministry of Health:** 026-13-25080 / 140-29-31940.

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