

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

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

Agisten® V 0.5 g Vaginal Tablet

Each vaginal tablet contains:

Clotrimazole 500 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 your illness get worse or if they do not improve after 7 days.

1. What is the medicine intended for?

A broad spectrum antimycotic medicine with fungicidal and trichomonocidal action, for single dose 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.

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.
- During your period because it is less effective then.

Special warnings regarding the use of the medicine Before the treatment with Agisten V 0.5 g, tell the physician if:

- You have had more than two infections of vaginal thrush during the last 6 months.
- You or your partner have had a sexually transmitted disease in the past.
- You are not sure if you have vaginal thrush or if this is the first time you suffer from these symptoms.
- You are aged under 16 or over 60 years of age.
- You have had an allergic reaction to Agisten V 0.5 g or other vaginal antimycotic products in the past.
- You suffer from any of the following symptoms:
 - Irregular vaginal bleeding.
 - Abnormal vaginal bleeding or blood-stained vaginal discharge.
 - Vaginal or vulval ulcers, blisters or sores.
 - Lower abdominal pain.
 - Difficulty or pain when passing urine.
 - Fever or chills.
 - Feeling sick (nausea) or being sick (vomiting).
 - Diarrhea.
 - Foul-smelling vaginal discharge.

This is because treatment with Agisten V 0.5 g may not be the right treatment for you.

- This product, like other products for intravaginal use, may reduce the efficacy of contraceptives made of rubber, such as: condoms or diaphragms. As a result, you should use alternative contraceptives for at least 5 days after using this product.
- During the treatment, do not use tampons, vaginal douches, spermicidal agents or other vaginal products.
- Avoid sexual intercourse when you have a fungal infection and during treatment, as your partner can be infected.

Children and adolescents

Agisten V 0.5 g is not intended for girls and adolescents under the age of 12.

Drug interactions

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

- Tacrolimus or sirolimus (medicines that reduce the immune system response in order to prevent the rejection of an organ after it has been transplanted).

Pregnancy, breastfeeding and fertility

If you are pregnant, breastfeeding or planning to become pregnant, tell the physician before using Agisten V 0.5 g. If you have already told the physician, follow his instructions carefully.

To treat internal vaginal thrush, the physician may recommend treatment with the tablets without the use of an applicator.

Driving and using machines

This medicine does not affect driving and/or the use of machines.

3. How to use Agisten V 0.5 g

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:

Insert 1 tablet into the vagina using the applicator in the evening before sleep.

Do not exceed the recommended dose.

- The symptoms of vaginal thrush should disappear within 3 days of treatment. If there is no improvement after 7 days, inform the physician.
- If the infection returns 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 physician.

This medicine is intended for intravaginal use only.

Do not put in mouth or swallow.

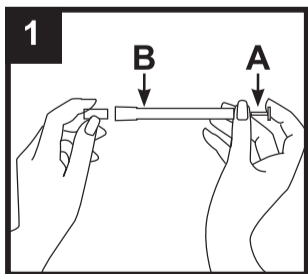
How to use:

If Agisten V 0.5 g is prescribed for you by a physician, follow his instructions. If you purchased the product without a physician's prescription, follow the following instructions:

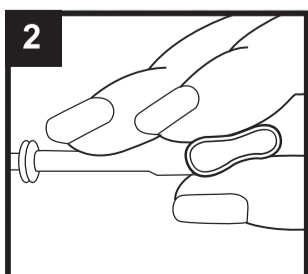
Use the applicator to insert the tablet as deeply as possible into the vagina, preferably before sleep for treatment convenience.

Wash your hands before removing the tablet from its 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).

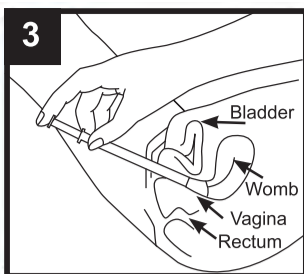


2. To fit the tablet into the applicator, squeeze the applicator end lightly on both sides. The tablet fits the applicator exactly and should be pressed to the end of the applicator up to a depth of about 1 cm.



3. Gently insert the applicator into the vagina as deeply as possible and as is comfortable, (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, 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 tablet. This does not indicate that the treatment did not work. If you notice pieces of the tablet that did not dissolve, refer to a physician 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 each day. Wiping with toilet paper should be done from front to back as a vaginal infection can be transmitted from the bowels. Replace the panty liner regularly. Avoid wearing nylon underwear and tight jeans. Avoid washing with perfumed soaps or using deodorants in the area of the vagina. Do not rub the area strongly with a wash sponge. Avoid warm baths with scented oils.

How can you contribute to the success of the treatment?

A partner can be infected and therefore it is recommended to avoid sexual intercourse or to use condoms for the entire duration of treatment. Likewise, it is recommended to consult the physician about the need for medication treatment of the partner too.

If you are using a medicine to wash the vagina between treatments, be careful not to instill the cleaning fluid firmly or in too large quantities so as not to instill the fluid into the womb – which could transmit the infection to there.

While using a vaginal medicine, staining of the underwear may occur.

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

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 0.5 g 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 all medicines, some people may be allergic to the vaginal tablets. If you are allergic, an allergic reaction will occur soon after using the product. If you experience an allergic reaction or worsened redness, burning, pain, itching or swelling, **stop using the product and proceed immediately to a physician** or a nearby hospital emergency room.

Signs of an allergic reaction may include:

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

After the use of Agisten V 0.5 g Vaginal Tablets you may experience: itching, rash, swelling, redness, 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 Agisten V 0.5 g

- 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.
- 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.
- Store in a cool place below 25°C.

6. Additional 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 does the medicine look like and what is the content of the package:

An Agisten V 0.5 g Vaginal Tablet package includes: One almost yellow white tablet, packaged in an aluminum blister and one applicator.

- **Manufacturer and registration holder:** Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.
- Revised in March 2023 according to MOH guidelines.
- Registration number of the medicine at the National Drug Registry of the Ministry of Health: 031-74-25210-00.

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