

AGISTEN V 0.2 gram Vaginal Tablets

Vaginal Tablets (for vaginal use)

Each tablet contains: Clotrimazole 200 mg

Inactive ingredients and allergens in the preparation - see section 6.

Read this 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. This medicine is intended for adolescent girls and women between the ages of 16 and 60. Patients under the age of 16 or over the age of 60 – consult the doctor.

Use the medicine properly.

Consult the pharmacist if you need further information.

The symptoms generally pass after 7 days of treatment. If there is no improvement in your condition within 3 days, consult the doctor.

1. WHAT IS THE MEDICINE INTENDED FOR?

Vaginal fungal infections primarily caused by *Candida* species.

Vaginal infections caused by trichomonas and microorganisms susceptible to clotrimazole.

Therapeutic group: Antifungals from the azole family.

2. BEFORE USING THE MEDICINE

❗ Do not use the medicine:

- if you are sensitive (allergic) to the active ingredient or to any of the other ingredients included in the medicine or to other antifungal agents from the same family.
- when menstruating since the treatment may be less effective.
- under the age of 12.

Special warnings regarding use of the medicine

This medicine may reduce the effectiveness of contraceptives made of rubber, such as: condoms or diaphragms made of latex. Therefore, it is recommended to use alternative contraceptives for at least 5 days after using the medicine.

During treatment and during a fungal infection, it is recommended to abstain from sexual intercourse, as the disease can be transmitted to your partner. Do not use tampons, vaginal douching preparations, spermicides or other vaginal preparations during the course of treatment.

❗ Before treatment with Agisten V 0.2 gram Vaginal Tablets, inform the doctor if

- you are sensitive to any food or medicine.
- you are unsure if you have a fungus or this is the first time you have these symptoms.
- you suffered from a vaginal infection more than twice within the past 6 months.
- you or your partner suffered in the past from a sexually transmitted disease.
- you are below the age of 16 or over the age of 60.
- you have had an allergic reaction to clotrimazole in the past or to other antifungal vaginal medicines.
- you have one of the following symptoms:
 - irregular vaginal bleeding
 - unusual vaginal bleeding or vaginal discharge with spots of blood
 - ulcers, blisters or sores in the vagina or on the vulva
 - lower abdominal pain
 - pain or difficulty in passing urine
 - fever or chills
 - nausea or vomiting
 - diarrhea
 - vaginal discharge with a bad odor

This is because treatment with **Agisten V 0.2 gram Vaginal Tablets** may not be the right treatment for you.

The treatment must be completed before initiation of menstruation.

❗ **If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.** It is particularly important to inform the doctor or pharmacist if you are taking:

a medicine called tacrolimus or sirolimus (medicines that reduce the immune system response, to prevent organ rejection after transplantation).

❗ Pregnancy and breastfeeding

If you are pregnant, trying to become pregnant or are breastfeeding, inform the doctor before using **Agisten V 0.2 gram Vaginal Tablets**. If you have already told your doctor, carefully follow his/her instructions.

For treatment of an internal fungal infection, the doctor may recommend treatment with the tablets without using an applicator.

❗ Young girls and adolescent girls

Do not use the medicine under the age of 12.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

Recommended dosage, unless instructed otherwise by the doctor:

One tablet in the evening before retiring, for 3 consecutive evenings (see "Directions for use").

Do not exceed the recommended dose.

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

Directions for use:

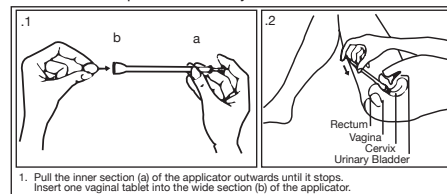
How to insert the medicine: First, wash your hands. Use the designated applicator. Follow the detailed instructions for use. If you are pregnant, check with the doctor if you can use the applicator to insert the medicine.

1. Remove the applicator from the packaging. Pull out the inner part of the device (figure 1:a) until it stops. Remove the tablet from the foil and place firmly in the wide part of the device (figure 1:b).

1. In the evening before retiring, lie on your back, with bent legs, and with your knees pointing upward. Insert the medicine, via the applicator, as deep into the vagina as you can, without using force or causing discomfort (see figure 2). Release the medicine by pushing the plunger. Wait a few minutes before getting up.
2. Wash your hands and the applicator thoroughly with soap and hot water and dry it after each use.

If the outer genital area is also irritated and/or red, apply Agisten cream.

Duration of treatment: three consecutive evenings; refer to the doctor if the signs of the disease (symptoms) worsen or do not improve after 7 days.



If someone accidentally swallowed the medicine, he/she should immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with him/her, even if he/she does not feel discomfort or there are no signs of poisoning.

If you forgot to take the medicine at the scheduled time, do not take a double dose. Take the next dose as soon as you remember. If you forgot for more than one day, the infection may not get the full treatment and therefore, if the symptoms persist after the treatment period, refer to a doctor.

How can you contribute to the success of the treatment?

Complete the treatment regimen as per the instructions.

The infection can be transmitted to your partner; therefore, be sure to abstain from sexual contact or to use a condom during intercourse throughout the treatment period. In addition, it is advisable to consult the doctor regarding the need for medicinal treatment for your partner as well.

To ensure contact between the tablet and moisture, so that it can fully dissolve, it is very important to insert it as deep as possible into the vagina.

Wear only cotton underwear and change them often. Stockings should also be changed daily.

Do not use a vaginal douche during treatment with **Agisten V 0.2 gram Vaginal Tablets**.

Underwear may become stained while using a vaginal medicine. In order to prevent such staining, use a sanitary pad or panty liner.

• If you notice pieces of the tablet that have not dissolved, refer to the doctor since the treatment may not have worked properly.

If you are pregnant – consult the doctor before use.

• 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 gram Vaginal Tablets** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Side effects that require special attention:

As with any medicine, some people may be allergic to the tablets. If you are allergic, an allergic reaction will occur soon after using the medicine. If you experience an allergic reaction or if the redness, burning, pain, itching or swelling worsen, stop using the medicine and refer to the doctor or closest emergency room immediately.

Signs of an allergic reaction: rash; problems swallowing or breathing; swelling of the lips, face, throat or tongue; weakness, dizziness or fainting; nausea. If these signs occur, stop the treatment and refer to a doctor immediately.

Additional side effects after starting treatment: itching, redness, rash, swelling, discomfort, burning, irritation or peeling of a layer of skin from the vaginal area, bleeding, pain in the abdomen or pelvic region.

If any of the side effects worsen, or if you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult the doctor or pharmacist immediately.

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 sight and reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from 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.

• Store in the original package.

• Do not dispose of medicines via the sink or waste bin. Ask the pharmacist how to dispose of medicines you no longer need. These measures will help protect the environment. Do not discard the applicator in the toilet.

6. FURTHER INFORMATION

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

• What the medicine looks like and the contents of the pack – 3 vaginal Tablets packaged in an aluminium blister and an applicator (insertion device).

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

• This leaflet was checked and approved by the Ministry of Health in December 2014.

• Registration number of the medicine in the National Drug Registry of the Ministry of Health: 2613.25080