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

This medicine is dispensed with a doctor's prescription only

Agisten V 0.5 g Vaginal Tablet

Each vaginal tablet contains:
Clotrimazole 500 mg.
Inactive ingredients: see section 6 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. Agisten V 0.5 g is a tablet for a single treatment of vaginal thrush. The tablet is inserted into the vagina, in the area of the infection. The medicine is intended for women between the ages of 16 and 60. Patients under the age of 16 or over the age of 60 – consult a doctor. This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

A broad-spectrum anti-fungal medicine, fatal to fungi and trichomonas, for topical treatment of vaginal infections.
Therapeutic group:
Antifungals from the azole group.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- You are sensitive (allergic) to the active ingredient or to other antifungals from the same family, or to any of the other ingredients contained in the medicine.
- You are under 12 years of age.
- You are menstruating or have vaginal bleeding. The treatment must be completed before the onset of menstruation.

Special warnings regarding use of the medicine

The symptoms of thrush should disappear within 3 days of treatment. If there is no improvement after 7 days, inform the doctor. If the infection recurs after 7 days, an additional treatment can be used; however, if you already suffered from two infections in the past six months, inform the doctor. If the effects recur within two months of completing treatment, consult the doctor. Recurrence of the effects can be related to another medical condition (such as diabetes) – conditions which require consultation with the doctor. During the course of treatment with this medicine, it is recommended to avoid sexual intercourse, as the disease can be transmitted to your partner. In addition, the effectiveness of latex contraceptives (natural rubber) is reduced when using Agisten V 0.5 g. As a result, it is recommended to use alternative contraceptives for at least 5 days after using this preparation. During the course of treatment, do not use tampons, vaginal douches, spermicides or other vaginal preparations.

Before treatment with Agisten V 0.5 g, inform the doctor if:
- You are pregnant or breastfeeding
- You are sensitive to any food or medicine
- You suffered more than twice from vaginal infection within the last 6 months
- You or your partner have suffered in the past from a sexually transmitted disease
- This is the first time you are suffering from a vaginal infection
- You are under the age of 16 or over the age of 60
- You have had in the past an allergic reaction to Agisten V 0.5 g or to other vaginal antifungal medicines
- You have any of the following symptoms:
  - Irregular vaginal bleeding or blood-stained vaginal discharge
  - Ulcers, blisters or sores in the vagina or vulva
  - Lower abdominal pain
  - Pain or difficulty passing urine
  - Fever or chills
  - Feeling sick or vomiting
  - Diarrhea
  - Foul-smelling vaginal discharge

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

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist before commencing treatment. It is especially important to inform the doctor or pharmacist if you are taking: A medicine called tacrolimus (a medicine which lowers the immune response in order to prevent rejection of an implanted organ).

Pregnancy: If you are pregnant or trying to become pregnant, inform the doctor before using Agisten V 0.5 g. If you have already informed the doctor, follow his instructions carefully.

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

Children and adolescents: Do not use this medicine below the age of 12.

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

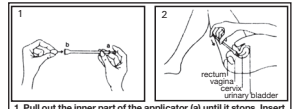
Important information regarding some of the components of the medicine: This preparation contains lactose. If you have an intolerance to lactose or other sugars, inform the doctor before starting treatment with this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are unsure about how the medicine is used. The dosage and the treatment regimen will be determined by the doctor only. The recommended dosage is usually: 1 tablet in the evening.

Attention: Do not swallow! This medicine is intended **for intravaginal use only.**

Directions for use: Wash your hands before removing the aluminum from the tablet and after using the applicator. Insert the tablet, using the enclosed applicator, as deeply as possible into the vagina, in the evening before going to sleep. The best way to do this is by lying on your back, with your knees slightly bent inward towards the body (see illustration 2). If the external area of the genitals is also irritated and/or red, apply Agisten cream.
- Transmission to your partner may occur; therefore, it is recommended to avoid sexual contact throughout the entire treatment period. In addition, it is advisable to consult the doctor regarding the need for medicinal treatment for your partner also.



1. Pull out the inner part of the applicator (a) until it stops. Insert one vaginal tablet into the wide part of the applicator (b).

How can you contribute to the success of the treatment?

Complete the treatment, according to the instructions. It is very important to insert the tablet as deeply as possible into the vagina, so that it will come into contact with moisture and completely dissolve. Wear cotton underwear only and change them often. Stockings should also be changed every day. Do not use a vaginal douche during treatment with Agisten V 0.5 g. When using the vaginal medicine, staining on the underwear may occur. A hygienic pad or a pantyliner can be used to prevent staining.
- If you notice pieces of the tablet that have not dissolved, refer to the doctor, as the treatment may not have worked properly.

Refer to the doctor if the symptoms persist after completion of treatment.

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. Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, 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 experience any of them.

Side effects which 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 preparation. If you experience an allergic reaction or worsened redness, burning, pain, itching or swelling, discontinue use of the preparation and immediately refer to a doctor or proceed to the closest emergency room.

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

Additional side effects after commencement of treatment: itching, rash, swelling, discomfort, burning, local irritation or peeling, pain in the abdomen or pelvic area. If one or more of these effects occur after commencing treatment, refer to a doctor or pharmacist immediately.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult a doctor immediately.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

Do not give this medicine to your relatives, neighbors or acquaintances.

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. Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the preparation! In any case of doubt, consult the pharmacist who dispensed the medicine to you.
- Do not discard medicines in wastewater or household garbage. Ask the pharmacist how to discard of medicines that you no longer need. Taking these measures will help preserve the environment.

Storage: Store in a cool place, at a temperature below 25°C.

Do not store different medications in the same package.

6. FURTHER INFORMATION:

In addition to the active ingredient, the medicine also contains the following inactive ingredients: Calcium lactate, Maize starch, Crospovidone, Lactic acid, Lactose monohydrate, Magnesium stearate, Hydroxypropyl methylcellulose, Microcrystalline cellulose, anhydrous colloidal silica.
- What the medicine looks like and the contents of the package:
  The preparation comes in a package of: one tablet packaged in a blister, and an applicator.
- 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 May 2013.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 31-74-25210