

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

The medicine is dispensed with a doctor's prescription only

# AGISTEN V 2% Vaginal Cream

## Clotrimazole 2%

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 has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

The 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.

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?

Broad spectrum antifungal medicine.  
**Therapeutic group:** Imidazole antifungal.

## 2. BEFORE USING THE MEDICINE

### Do not use the medicine:

- if you are sensitive (allergic) to the active ingredient, to cetostearyl alcohol, 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.

## Special warnings regarding use of the medicine

During treatment, abstain from vaginal intercourse, as the disease can be transmitted to your partner.

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.

Do not use tampons, vaginal douching preparations, spermicides or other vaginal preparations during the course of treatment.

## Before treatment with Agisten V 2% Vaginal Cream, 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 or to cetostearyl alcohol or to other antifungal vaginal medicines in the past.
- If you have one of the following symptoms:
  - irregular vaginal bleeding.
  - unusual vaginal bleeding or blood-stained vaginal discharge.

- 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.
- foul-smelling vaginal discharge.

This is because treatment with Agisten V 2% Vaginal Cream 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 of 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 2% Vaginal Cream. If you have already told your doctor, carefully follow his/her instructions.

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

## Important information about some of the ingredients in the medicine

The medicine contains cetostearyl alcohol which may cause local skin irritation (e.g., rash, itching or redness).

## 3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain. The dosage and treatment regimen will be determined by the doctor only.

Recommended dosage, unless instructed otherwise by the doctor: Use the cream in the evening before retiring, for 3 consecutive evenings.

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

Directions for use:

1. How to insert the medicine: First, wash your hands. Follow the detailed instructions for use.
2. Remove the cap from the tube and attach the wide side of the applicator to the end of the tube (a). Squeeze gently at the bottom of the tube thus instilling the medication into the applicator. The applicator is filled when the plunger (b) reaches its stopping point. Release the applicator from the tube and replace the cap on the tube.

3. Lie on your back, with bent legs, and push 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. Release the medicine by pushing the plunger. Wait a few minutes before getting up (see figure 2).
4. Use a new applicator every time you insert the cream into the vagina.

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 this medicine at the scheduled time, do not use a double dose. Use 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 completion of the treatment period, refer to the doctor. Adhere to the treatment as recommended by the doctor.

## How can you contribute to the success of the treatment?

Complete the treatment regimen as per the instructions.

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 2% Vaginal Cream.

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

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 medical treatment for your partner as well.

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 2% Vaginal Cream 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 patients may be allergic to the cream. 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, local irritation, 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 the doctor immediately.

Additional side effects after starting treatment: itching, rash, swelling, redness, discomfort, burning, irritation or vaginal peeling, bleeding or 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 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 an 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 the original package, in a cool place below 25°C.
- After first opening can be used for 3 months.
- 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 - 2-Octyldodecanol, Cetostearyl alcohol, Cetyl esters wax, Sorbitan monostearate, Polysorbate 60, Benzyl alcohol, Purified water.
- Concentration of the preservative agent: Benzyl alcohol 1.044%
- What the medicine looks like and the contents of the pack:  
An aluminium tube containing 20 g of white cream and 3 applicators (insertion devices).
- 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: 4856.23822

