

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% w/w

Inactive and allergenic ingredients in the medicine – see section 6 “Further information” and in section 2 “Important information about some of the ingredients in the medicine” of 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.

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.

Refer to the doctor if symptoms of the illness worsen or are not improving after 7 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

Agisten V 2% Vaginal Cream in a broad spectrum antimycotic with fungicidal action.

Therapeutic group:

Azole group antifungal. Vaginal thrush is a common infection most women suffer from at some stage in life and is not caused by poor personal hygiene. The cause of vaginal thrush is a fungus called Candida, which lives harmlessly in the vagina and other parts of the body, without you even noticing it.

However, the natural balance that keeps Candida under control can be upset by several factors, such as hormonal changes (menstrual cycle, oral contraceptives, pregnancy, menopause), poor health, use of antibiotics, scented soaps, bath supplements and tight-fitting clothes.

A change in the natural pH balance may lead to an increase in fungal growth that may develop into thrush. This can manifest by the following symptoms: persistent burning sensation and/or itch around the vagina and vulva, redness, swelling and pain in the vaginal and vulval tissues and white, odorless vaginal discharge. You may not suffer from all the symptoms detailed, but only from one of them.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- if you are sensitive (allergic) to the active ingredient (clotrimazole), to cetostearyl alcohol or to any of the additional ingredients contained in the medicine (see section 6 “Further information”).
- during your period, as the treatment may be less effective.

Special warnings regarding use of Agisten V 2% Vaginal Cream

Before treatment with Agisten V 2% Vaginal Cream, tell the doctor if:

- you are not sure that you are suffering from a fungal infection or if this is the first time you are suffering from these symptoms.
- you suffered from more than two fungal infections in the last 6 months.
- you or your partner has ever suffered from a sexually transmitted disease.
- you are under the age of 16 years or over the age of 60 years.

you have ever had a allergic reaction to Agisten V or to other vaginal antifungal medicines.

- you have one of the following symptoms:
 - irregular vaginal bleeding.
 - abnormal vaginal bleeding or bloody discharge.
 - vaginal or vulval ulcers, blisters or sores.
 - lower abdominal pain.
 - pain or difficulty in passing urine.
 - fever or chills.
 - nausea or vomiting.
 - diarrhoea.
 - a foul-smelling vaginal discharge.

This is because treatment with Agisten V 2% Vaginal Cream is not the right treatment for you.

- As with other medicines for intravaginal use, this medicine may reduce the effectiveness of rubber contraceptives such as a condom or diaphragm. Therefore, use alternative contraceptives for at least 5 days after using the medicine.
- Do not use tampons, intravaginal douches, spermicides or other vaginal medicines during the course of treatment with this medicine.
- Avoid vaginal intercourse for as long as you are suffering from vaginal thrush or are using this medicine, since your partner may become infected.

Girls and female adolescents

Agisten V 2% Vaginal Cream is not intended for use by girls and female adolescents under 12 years of age.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking: tacrolimus or sirolimus (intended to reduce the immune reaction to prevent implant rejection after an organ transplantation).

Pregnancy, breastfeeding and fertility

If you are pregnant, trying to become pregnant or are breastfeeding, tell the doctor before using Agisten V 2% Vaginal Cream. If you have already told the doctor, follow his/her instructions carefully.

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

Important information about some of the ingredients of the medicine

Agisten V 2% Vaginal Cream contains cetostearyl alcohol, which may cause localized skin irritation (rash, itching or redness) and benzyl alcohol, which may cause mild localized irritation and allergic reactions.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by the doctor only.

The recommended dosage is usually:

Use the cream at bedtime, for 3 consecutive nights.

Do not exceed the recommended dose.

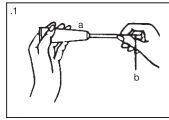
Mode of use:

- Do not put into the mouth or swallow!
- This medicine is intended for vaginal use.

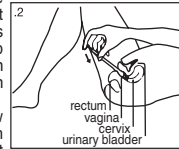
Instructions for use:

Follow the detailed instructions.

1. Wash your hands. Remove the tube cap and place the wide side of the applicator against the edge of the tube (a). Squeeze gently on the bottom of the tube so that the cream will enter and fill the applicator. The applicator is full when the plunger (b) reaches the stopping point. Release the applicator from the tube and screw the tube cap back on.



2. Insert the applicator containing the cream into the vagina as deeply as possible, so long as no discomfort is caused (the best way to do this is while lying on your back with your knees bent upwards). Insert the cream into the vagina by pressing the plunger. Wait several minutes before getting up from lying down (see illustration 2).



3. Use a new applicator each time you insert the cream into the vagina.

- Complete the treatment according to the instructions.
- Do not use a vaginal douche product during the course of treatment with Agisten V 2% Vaginal Cream.
- Underwear may be stained while using the cream and inserting it into the vagina. To prevent staining, a pad or pantyliner can be used.
- To avoid future recurrence, be sure to: wear only cotton underwear and avoid tight-fitting clothing and stockings. Shower every day, after going to the toilet wipe yourself from the front to back, change hygienic pads every day, avoid using scented soaps or vaginal deodorants, avoid scrubbing with a bath sponge and avoid hot baths.

If you accidentally used a higher dosage, if a child or someone else accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to apply the medicine at the scheduled time

Do not use a double dose. Apply the next dose as soon as you remember.

If you forgot for more than one day, the infection may not be fully treated; therefore, if the symptoms persist after completing the treatment period, refer to a doctor.

Adhere to the treatment regimen as recommended by the doctor.

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 by the list of side effects. You may not suffer from any of them.

Side effects requiring special attention:

As with all medicines, some patients may be allergic to the cream. If you are allergic, an allergic reaction may develop soon after using the medicine.

Stop the treatment and refer immediately to a doctor or proceed to the closest emergency room if an allergic reaction or worsening of the redness, burning sensation, pain, itch or swelling occurs.

Signs of an allergic reaction include:

- rash.
- swallowing or breathing problems.
- swelling of the lips, face, throat or tongue.
- weakness, dizziness or faintness.
- nausea.

Side effects that may occur after applying the cream:

- itching, redness, rash, swelling, discomfort, burning, irritation, peeling in the vagina or bleeding.
- pains in the abdomen or pelvic area.
- nausea.

If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

In addition, they can be reported to Padagis via the following address: Padagis.co.il

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 reach and sight of children and/or infants to avoid poisoning.
- Do not induce vomiting unless explicitly instructed to do so by 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. The cream can be used for 6 months after first opening.
- Store in a cool place below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, Agisten V 2% Vaginal Cream also contains: 2-Octyldodecanol, Cetostearyl alcohol, Cetyl esters wax, Sorbitan monostearate, Polysorbate 60, Benzyl alcohol, Purified water.

• What Agisten V 2% Vaginal Cream looks like and the contents of the package: Agisten V 2% Vaginal Cream is packaged in an aluminum tube that contains 20 grams of a white cream, and 3 applicators.

Registration holder and manufacturer: Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.

- Revised in August 2024
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 048-56-23822

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08/2024 30200769 SH109063 PL V1