

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

The medicine is dispensed without a doctor's prescription

Canesten V

Vaginal tablets (for intravaginal use)

Active ingredients:

Clotrimazole 200 mg

Inactive ingredients: See section 6 "Further Information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, contact the doctor or pharmacist.

Use this medicine according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need further information. Consult your doctor if your symptoms of illness get worse or do not improve in 7 days.

1) What is the medicine intended for?

Canesten V is an antifungal preparation for the treatment of infections in the vagina and external female genitalia, caused by the following infectious agents: *Candida albicans* and *trichomonas* (flagellates).

Vaginal inflammation caused by *trichomonas* requires combined treatment with Canesten V and oral metronidazole.

Therapeutic group: Antifungals from the azole group.

Vaginal thrush is a common infection that most women suffer from at some time in their lives and is not caused by poor personal hygiene.

Vaginal thrush is caused by a fungus called *Candida* which lives harmlessly in the vagina and other organs unnoticed by you. However, the natural balance that keeps *Candida* under control can be affected by several factors such as hormonal changes (menstruation, contraceptive pill, pregnancy, menopause), poor health, antibiotics, perfumed soaps, bath additives and tight clothing.

If the natural pH balance is altered, the level of fungus growth increases and can develop into an infection causing any of the following symptoms: persistent burning and/or itching sensation around the vagina and vulva, redness, swelling and soreness of the tissues of the vagina and vulva and a white, odourless discharge from the vagina. You might not have all these symptoms; but only have one of them.

2) Before using the medicine

Do not use the medicine:

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| <ul style="list-style-type: none">• If you are sensitive (allergic) to the active ingredient (clotrimazole) or to any of the other ingredients contained in the medicine (see section 6 "Further Information"). |
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Special warnings regarding the use of the medicine:

- **Use this medicine only if a doctor had previously diagnosed you with vaginal thrush.**

Before the treatment with Canesten V, contact the doctor if:

- You are uncertain whether you have vaginal thrush, or if this is the first time you have had these symptoms.
- You have had more than two vaginal thrush infections in the last 6 months.
- You or your partner have ever had a sexually transmitted disease.

- You are under the age of 16 years, or over the age of 60 years.
- You have ever had an allergic reaction to Canesten V or to other vaginal antifungal preparations.
- In the event of occurrence of any of the following symptoms, Canesten V may not be the appropriate treatment for you:
 - o Irregular vaginal bleeding.
 - o Abnormal vaginal bleeding or bloody discharge.
 - o Ulcers, blisters or sores in the vagina or vulva.
 - o Lower abdominal pain.
 - o Pain or difficulty in passing urine.
 - o Fever or chills.
 - o Nausea or vomiting.
 - o Diarrhoea.
 - o A foul-smelling discharge from the vagina.
- Canesten V, like other preparations for intravaginal use, may reduce the effectiveness of rubber contraceptives, such as a condom and diaphragm. Therefore, you must use alternative contraceptives for at least 5 days after treatment with this medicine.
- Do not use tampons, intravaginal douches, spermicides or other vaginal preparations during the course of treatment with this medicine.
- Avoid vaginal intercourse while you have vaginal thrush and during use of Canesten V, because your partner could become infected.

Girls and adolescent girls

This medicine is intended for use in women, girls and adolescent girls aged 12 years and up.

Drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.

- Tell your doctor or pharmacist especially if you are taking tacrolimus or sirolimus (intended to reduce the immune system response in order to prevent graft rejection after an organ transplant).

Pregnancy, breastfeeding and fertility

Pregnancy:

If you are pregnant, breastfeeding or trying to conceive, consult your doctor or pharmacist before using the medicine and follow their instructions carefully. Clotrimazole may be used during pregnancy, but only under the supervision of a doctor. Do not use the applicator during your pregnancy.

Breastfeeding:

There are no data regarding passage of the medicine into breast milk. Absorption into the circulation after use of the medicine is minimal, therefore it is unlikely to cause systemic effects. The medicine can be used during breastfeeding.

Fertility:

No studies on the effect of the medicine on human fertility have been conducted. However, animal studies have demonstrated no effect on fertility.

Driving and use of machines

The medicine has no or a negligible influence on the ability to drive or operate machines.

3) How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dosage is usually:

One tablet for intravaginal insertion in the evening before bedtime for 3 consecutive evenings (see section "Manner of using the medicine").

Do not exceed the recommended dose.

Treatment duration:

- The symptoms of fungal infection should disappear within 3 days following treatment initiation. If no improvement in your condition is seen after 7 days, contact a doctor.
- In case of recurrence of the fungal infection after 7 days, you can use an additional treatment, but if you have more than two infections within 6 months, you should contact a doctor.

Manner of use:

- **For intravaginal use only.** Do not put in your mouth or swallow.

If you have accidentally taken an overdose, accidentally swallowed the tablet, or if a child has accidentally swallowed some of the medicine, contact a doctor immediately or go to a hospital emergency room and bring the medicine package with you.

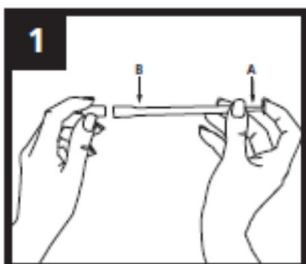
How to use this medicine – general instructions:

If the medicine has been prescribed to you by a doctor, you should follow their instructions.

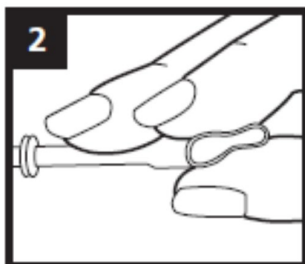
If you have purchased the medicine without a doctor's prescription, you should use the medicine as described in this section. The applicator supplied with the medicine is intended to assist with inserting the tablet into the vagina as deep as possible, preferably before going to sleep, **for three consecutive evenings**.

Wash your hands before removing the tablet from the pack and again after you have finished using the special applicator. If you are pregnant, do not use the applicator to insert the medicine.

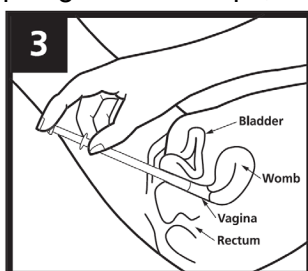
1. Remove the applicator from the package. Pull out the plunger (A) until it stops. Remove the vaginal tablet from the aluminium blister and place it in the wide part of the applicator (B).



2. To fit the tablet into the applicator, the edge of the applicator should be slightly squeezed at both sides. The tablet fits tightly into the applicator and should be squeezed up to a depth of 1 cm.



3. Insert the applicator containing the tablet as deeply as possible, without causing discomfort, into the vagina (the best way to do this is while lying on your back, with your legs bent and the knees facing up). Holding the applicator in place, slowly press the plunger until it stops, so that the tablet is deposited into the vagina.



4. Remove the applicator. After use, completely remove the plunger (A) from the applicator (B). Wash it in warm (not boiling) soapy water and dry carefully.
5. After completing the treatment, dispose of the applicator in a safe place, out of the reach of children. The applicator cannot be flushed down the toilet.
 - The intravaginal tablet dissolves in the vagina and therefore, it is advisable to wear a panty liner since it is quite common to notice a white residue after using the medicine. This does not mean that the treatment has not worked properly. However, if you notice whole pieces of undissolved tablet fragments, the treatment may not have worked properly, and you should contact the doctor or pharmacist.
 - To prevent future recurrence: wear only cotton underwear, which is not too tight, and change it frequently. Shower daily. Wiping yourself in the toilet should be performed from front to back, since fungal infection may be transmitted from the bowel. Avoid wearing clothes which are too tight and nylon stockings. Avoid washing yourself with perfumed soaps or using vaginal deodorants. Do not rub the area firmly with a sponge. Avoid hot baths with strongly perfumed oils.
- **If you forget to use this medicine at the required time**
 - Use a dose as soon as you remember and continue the rest of the treatment as usual.
 - If you have forgotten for more than one day, your vaginal infection may not be fully treated. Therefore, if the symptoms persist upon completion of the treatment, you should contact the doctor.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult your doctor or pharmacist.

4) Side effects

As with any medicine, the use of Canesten V 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 any medicine, some people may be allergic to it. If you are sensitive (allergic) to the preparation, an allergic reaction will occur shortly after inserting the medicine. **Stop the treatment and contact a doctor immediately or go to the nearest hospital emergency room** if an allergic reaction develops, or the redness, burning sensation, pain, itching or swelling get worse.

Signs indicating an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue, weakness, dizziness or fainting, nausea.

Effects which may occur after using the intravaginal tablet:

- Itching, rash, swelling, redness, discomfort, burning, irritation, vaginal peeling, vaginal discharge or bleeding.
- Pain in the abdomen or pelvic area.
- Nausea.

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

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5) How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept 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 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.
- Do not throw away medicines via wastewater or household waste. Consult your pharmacist how to throw away a medicine which is no longer used. These measures will help protect the environment.
- **Storage conditions:** Store below 25°C.

6) Further information

- **In addition to the active ingredient, this medicine also contains:**
Lactose monohydrate, microcrystalline cellulose, maize starch, crospovidone, lactic acid, magnesium stearate, calcium lactate pentahydrate, colloidal anhydrous silica, hypromellose 15 cP.
- **What does the medicine look like and what is the content of the pack:**
A pack of Canesten V contains 3 white vaginal tablets packed in an aluminium blister and one applicator for insertion of the tablet into the vagina. Each tablet is oblong and white, with "Bayer" imprinted on one side and "NR" on the other side.
- **Registration holder/importer's name and address:**
Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 149 92 33642 02

Revised in November 2021 according to MoH guidelines.