

## Package leaflet: Information for the user

### Canesten 500 mg soft vaginal capsule clotrimazole

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

#### What is in this leaflet

1. What Canesten soft vaginal capsule is and what it is used for
2. What you need to know before you use Canesten soft vaginal capsule
3. How to use Canesten soft vaginal capsule
4. Possible side effects
5. How to store Canesten soft vaginal capsule
6. Contents of the pack and other information

#### 1. What Canesten soft vaginal capsule is and what it is used for

The active substance in Canesten soft vaginal capsule is clotrimazole, which belongs to the group of imidazoles. It has a broad effect against fungi, i.e. it destroys fungi and inhibits their growth. It is also effective against micro-organisms such as dermatophytes, yeasts and moulds.

Canesten soft vaginal capsule is used to **treat infections of the vagina and external female genital organs caused by clotrimazole-sensitive microorganisms**. The infections are usually caused by Candida yeast fungus. Symptoms include itching, burning, and thick, white to yellow, odourless vaginal discharge (cottage cheese-like), redness, swelling and soreness.

This medicine is used in adults and adolescents aged 16 years and older.

#### 2. What you need to know before you use Canesten soft vaginal capsule

##### Do not use Canesten soft vaginal capsule:

- if you are allergic to clotrimazole or any of the other ingredients of this medicine (listed in section 6).

##### Warnings and precautions

Talk to your doctor before using Canesten soft vaginal capsule if you have:

- your first vaginal infection
- vaginal infection during the first trimester of your pregnancy
- recurrent infections, more than two infections during the previous six months
- fever of 38°C or more
- pain in the lower abdomen, back pain
- foul-smelling vaginal discharge
- nausea
- vaginal bleeding and/or simultaneous pain in the shoulders

Canesten soft vaginal capsule is not recommended during the menstrual period. The treatment should be finished before the onset of menstruation.

Do not use tampons, vaginal rinses, products that kill sperm or other products intended for vaginal use, at the same time as Canesten soft vaginal capsule.

Avoid sexual intercourse during use of the medicine because the infection may be transmitted to your sexual partner.

If your sexual partner has symptoms of yeast infection, these should be treated at the same time. Treatment of sexual partners might help prevent reinfection.

The contraceptive properties of latex contraceptives, such as condoms and diaphragms, may be reduced.

Do not swallow Canesten soft vaginal capsules.

### **Children and adolescents**

In adolescents aged less than 16 years Canesten soft vaginal capsule should not be used without a doctor's prescription [OTC].

### **Other medicines and Canesten soft vaginal capsule**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Contact your doctor if you are taking **tacrolimus** or **sirolimus**, medicines used to control the body's immune response after organ transplantation.

It is also possible that the concentration of certain medicines might increase if they are used concomitantly with Canesten vaginal soft capsule. However, with a single 500 mg dose it is unlikely that this will occur. Ask your doctor or pharmacist for advice if you are unsure about using a medicine at the same time as Canesten vaginal soft capsule.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

- **Pregnancy**

During the first 3 months of pregnancy, you should consult your doctor before using clotrimazole. During pregnancy, **do not use the provided applicator**. Therefore, insert the soft vaginal capsule into the vagina with a finger, to prevent injuries to the uterine cervix.

- **Breast-feeding**

Canesten soft vaginal capsule can be used during breast-feeding. Ask your doctor or pharmacist for advice.

### **Driving and using machines**

Canesten soft vaginal capsule has no effect on the ability to drive and use machines.

## **3. How to use Canesten soft vaginal capsule**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. [OTC]

The recommended dose is:

- one soft vaginal capsule inserted deep into the vagina as a single dose in the evening.

Treatment can be repeated. However, if the infection persists or keeps coming back, it may indicate a more serious condition and medical advice should be sought.

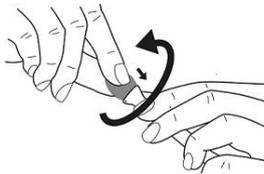
### **Instruction for use**

The soft vaginal capsule should be inserted as deeply in the vagina as possible with the provided applicator, preferably in lying position, in the evening before sleep.

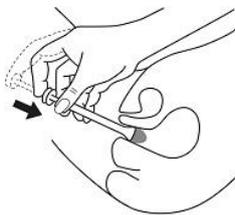
1. Pull the applicator's plunger outward until it stops. Put the soft vaginal capsule in the applicator.



2. Place the soft vaginal capsule firmly in the applicator's holder by twisting it gently.



3. Insert the loaded applicator deep into the vagina. This is best achieved when lying back with the legs slightly drawn up. Press the plunger completely inside the applicator. Remove the applicator with the plunger pressed in.



Inserting the soft vaginal capsule without an applicator:

If you are pregnant insert the vaginal soft capsule into the vagina with your fingers.

### **Duration of treatment**

Canesten soft vaginal capsule is used as a single dose treatment.

**Contact a doctor** if symptoms have not improved **after 7 days** from start of the treatment, to confirm the cause of the infection. If the symptoms become worse, contact a doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects can occur with the following frequencies:

**Common**, may affect up to 1 in 10 people:

- burning

**Uncommon**, may affect up to 1 in 100 people:

- abdominal pain
- itching
- skin reddening/irritation

**Rare**, may affect up to 1 in 1000 people:

- allergic reactions
- swelling
- skin rash
- vaginal bleeding

**Frequency not known**, according to available data

- vaginal exfoliation
- vaginal discomfort
- vaginal pain
- nausea
- urticaria
- vaginal discharge
- pain

**Stop the treatment** if you have local side effects or allergic reaction (including anaphylactic reaction, angioedema (swelling), low blood pressure, shortness of breath and/or fainting).

Local reactions may be similar to the symptoms of the disease. Therefore, it may sometimes be difficult to differentiate the symptoms of infection from the adverse effects caused by the medicine.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [www.ravimiamet.ee](http://www.ravimiamet.ee). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Canesten soft vaginal capsule**

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the package after “Kõlblik kuni:”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What Canesten vaginal soft capsule contains**

- The active substance is clotrimazole.
  - Each soft vaginal capsule contains 500 mg of clotrimazole.
- The other ingredients are:
  - gelatin
  - glycerol
  - paraffin, white soft; paraffin, liquid
  - purified water
  - titanium dioxide (E171)

- quinoline yellow (E104)
- sunset yellow (E110)
- lecithin (E322)
- triglycerides, medium-chain

#### **What Canesten soft vaginal capsule looks like and contents of the pack**

One yellow vaginal soft capsule in a foil package and an applicator, both enclosed in a cardboard carton.

#### **Marketing Authorisation Holder and manufacturer**

##### Marketing Authorisation Holder:

UAB Bayer  
Sporto 18  
LT-09238 Vilnius  
Lithuania

##### Manufacturer:

GP Grenzach Produktions GmbH  
Emil-Barell-Strasse 7  
79639 Grenzach-Wyhlen  
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Bayer OÜ  
Lõõtsa 12  
11415 Tallinn  
Tel: 655 85 65

#### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria: Canesten Clotrimazol 0,5 g Weichkapsel zur vaginalen Anwendung  
Croatia: Canesten 1 500 mg meka kapsula za rodnicu  
Cyprus: Gyno-Canesten 500 mg κολπικό καψάκιο, μαλακό  
Czech Republic: Canesten Gyn 1 den  
Estonia: Canesten  
Finland: Canesten 500 mg emätinpuikko pehmeä kapseli  
Greece: Gyno-Canesten 500 mg κολπικό καψάκιο, μαλακό  
Italy: Gyno-Canesten Monodose  
Latvia: Canesten  
Lithuania: Canesten  
Poland: Canesten  
Romania: Canesten Gyn Uno 500 mg capsula moale vaginala  
Slovakia: Canesten Gyn 1 deň 500 mg mäkká vaginálna kapsula  
Slovenia: Canesten1 500 mg mehka vaginalna kapsula

**This leaflet was last revised in May 2021.**

#### **Other sources of information**

Detailed information on this medicine is available on the State Agency of Medicines web site:  
<http://www.ravimiamet.ee/>.