

# Canesten<sup>®</sup> Soft Vaginal Capsule Combi

## 500mg Soft Vaginal Capsule & 2% w/w Cream

Clotrimazole

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have 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 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<sup>®</sup> Combi is and what it is used for
2. What you need to know before you use Canesten<sup>®</sup> Combi
3. How to use Canesten<sup>®</sup> Combi
4. Possible side effects
5. How to store Canesten<sup>®</sup> Combi
6. Contents of the pack and other information

### 1. WHAT CANESTEN<sup>®</sup> COMBI IS AND WHAT IT IS USED FOR

Canesten<sup>®</sup> Soft Vaginal Capsule Combi is a complete treatment for vaginal thrush because it treats both the internal cause and the external symptoms.

**Only use this product if you have been previously diagnosed by your doctor as having vaginal thrush.**

The active substance in Canesten<sup>®</sup> Soft Vaginal Capsule Combi is clotrimazole. Clotrimazole belongs to a group of medicines called azoles and is an antifungal agent which fights the cause of infections such as vaginal thrush.

Some women suffer from recurrent attacks of thrush. To reduce the frequency of these attacks, the sexual partner's penis can be treated with this cream to prevent reinfection, even if they have no symptoms of thrush.

### 2. WHAT YOU NEED TO KNOW BEFORE YOU USE CANESTEN<sup>®</sup> COMBI

**Do not use Canesten<sup>®</sup> Soft Vaginal Capsule Combi:**

- If you are allergic to clotrimazole or any of the other ingredients, including cetostearyl alcohol, benzyl alcohol or soya oil, of Canesten<sup>®</sup> Soft Vaginal Capsule Combi (listed in Section 6).

#### Warnings and precautions

**Talk to your doctor or pharmacist before using Canesten<sup>®</sup> Soft Vaginal Capsule Combi if:**

- You are unsure whether you have thrush or this is the first time you have had these symptoms.
- You have had more than two infections of thrush in the last six months.
- You or your partner have ever had a sexually transmitted disease.
- You are aged under 16 or over 60.
- You have ever had an allergic reaction to Canesten<sup>®</sup> or any of the other ingredients (listed in section 6).

- You have any of the following symptoms:
  - Irregular vaginal bleeding.
  - Abnormal vaginal bleeding or a blood-stained discharge.
  - Ulcers, blisters or sores of the vagina or vulva.
  - Lower abdominal pain.
  - Back pain.
  - Shoulder pain.
  - Pain or difficulty in passing urine.
  - Fever or chills.
  - Feeling sick or vomiting.
  - Diarrhoea.
  - A foul smelling discharge from the vagina.

This is because Canesten® Soft Vaginal Capsule Combi may not be the right treatment for you.

**Canesten Soft Vaginal Capsule Combi contains cetostearyl alcohol, soya oil and benzyl alcohol**

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

Canesten® Soft Vaginal Capsule Combi contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

This product contains 20 mg benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions. Benzyl alcohol may cause mild local irritation.

**Special precautions:**

As with other creams and soft vaginal capsules, this product may reduce the effectiveness of rubber contraceptives, such as condoms or diaphragms. Consequently, you should use alternative precautions for at least five days after using this product.

Do not use tampons, intravaginal douches, spermicides or other vaginal products while using this product.

Avoid vaginal intercourse while you have thrush and during use of this product because your partner could become infected.

Do not use this product during your period as it may be less effective.

**Children**

Not for use in children under 16.

**Other medicines and Canesten Soft Vaginal Capsule Combi:**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Inform your doctor if you are taking tacrolimus or sirolimus (used to reduce the immune response to prevent rejection after an organ transplant).

**Pregnancy and breastfeeding:**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Canesten Soft Vaginal Capsule Combi can be used in pregnancy and breastfeeding, but only under the supervision of your doctor or midwife. You must follow his/her instructions for use.

Use of the applicator is not advised during pregnancy.

### 3. HOW TO USE CANESTEN® COMBI

If Canesten® Soft Vaginal Capsule Combi has been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely.

#### The Soft Vaginal Capsule:

The applicator should be used to insert the soft vaginal capsule as high as possible into the vagina, preferably before going to sleep at night for convenient and comfortable treatment.

Wash your hands before removing the foil from the blister pack and again afterwards when you have used the applicator.

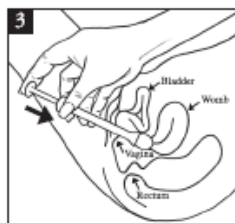
1. Remove the applicator from the packaging. Pull out the plunger A until it stops. Remove the soft vaginal capsule from the foil blister pack and place firmly into the applicator B.



2. Fix the soft vaginal capsule firmly into the designated holder of the applicator B, by a light twist. The soft vaginal capsule fits tightly into the applicator.



3. Carefully put the applicator as deep as is comfortable into the vagina (this is easiest when lying on your back with your knees bent up). Holding the applicator in place, slowly press the plunger until it stops so that the soft vaginal capsule is deposited into the vagina.



4. Remove the applicator. Dispose of the applicator in a safe place, out of the reach of children. The applicator cannot be flushed down the toilet.

Since the soft vaginal capsule dissolves in the vagina, it may be helpful to wear a panty liner.

#### The Cream:

Before use, pierce the tube seal by inverting the cap over the end of the tube and press.

**Women:**

To treat the itching and soreness of the vulva (vulvitis), the cream should be thinly and evenly applied to the area around the entrance of the vagina, 2 or 3 times a day and smoothed in gently. Treatment should be continued until symptoms of the infection disappear.

**Treating your sexual partner:**

If your sexual partner is treated with this cream, the cream should be applied to the end of the penis 2 or 3 times a day for up to two weeks.

The symptoms of thrush should disappear within three days of treatment. If no improvement is seen after seven days you must tell your doctor. If the infection returns after seven days you may use one further treatment, but if you have more than two infections within six months you should see your doctor.

**Canesten® Soft Vaginal Capsule is for use in the vagina only. The cream is for external use only:**

Do not put the soft vaginal capsule or cream in your mouth or swallow them.

If the soft vaginal capsule or cream are swallowed accidentally, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

Avoid contact with the eyes.

**4. POSSIBLE SIDE EFFECTS**

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

As with all medicines, some people may be allergic to the soft vaginal capsule or cream. If you are allergic, a reaction will occur soon after you have used the medicine. If you experience an allergic reaction or the redness, burning, pain, itching or swelling get worse, stop using this product and tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital. Signs of an allergic reaction may include:

- Rash.
- Swallowing or breathing problems.
- Swelling of your lips, face, throat or tongue.
- Weakness, feeling dizzy or faint.
- Nausea.
- Low blood pressure.

Other side effects which have been reported:

- Mild burning, irritation
- Discomfort of the vagina or vulva, redness, swelling, bleeding, peeling skin in the genital area, itching, rash, vaginal discharge, Pain (e.g. abdominal or pelvic area).

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA

Pharmacovigilance; Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE CANESTEN® COMBI**

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

Do not store above 25°C.

Do not use ~~the~~ this medicine after the expiry date which is stated on the carton, on the foil blister strip of the soft vaginal capsule and on the end of the tube of cream. 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 to protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What Canesten® Soft Vaginal Capsule Combi contains:

#### Soft Vaginal Capsule:

- The active substance is clotrimazole at a strength of 500mg.
- The other ingredients are white soft paraffin, liquid paraffin, gelatin, glycerol, titanium dioxide (E171), quinoline yellow (E104), sunset yellow (E110), lecithin (source of soya oil), medium-chain triglycerides.

#### Cream:

- The active substance is clotrimazole at a strength of 2% w/w.
- The other ingredients are benzyl alcohol, polysorbate 60, sorbitan stearate, cetyl palmitate, cetostearyl alcohol, octyldodecanol and purified water.

See Section 2 'Important information about some of the ingredients' for cetostearyl alcohol, benzyl alcohol and soya oil advice.

### What Canesten® Soft Vaginal Capsule Combi looks like and contents of the pack:

Canesten® Soft Vaginal Capsule Combi contains a full course of treatment, which consists of a single yellow teardrop-shaped soft vaginal capsule held inside a foil blister pack, one applicator for insertion of the soft vaginal capsule into the vagina and one 10g tube of white external cream.

### Marketing Authorisation Holder:

Bayer Ltd., The Atrium, Blackthorn Road, Dublin 18.

**Manufacturer:** GP Grenzach Produktions GmbH, 79639 Grenzach-Wyhlen, Germany.

**Remember: If you have any doubts about using Canesten® Soft Vaginal Capsule Combi correctly, seek the advice of your doctor or pharmacist.**

### Further information about vaginal thrush:

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

Thrush is caused by a yeast (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 many 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 yeast increases and can develop into a thrush infection causing any of the following symptoms: persistent burning and/or itching around the vagina and vulva, redness, swelling and soreness of the tissues of the vagina and vulva and a whitish, odourless discharge from the vagina. Not everybody who has thrush has all these symptoms; you may have only one of them.

#### How to avoid future recurrences:

- ✓ Wear cotton knickers and loose clothing.
- ✓ Wash daily.
- ✓ After going to the toilet, wipe yourself from the front to back as a thrush infection may be transferred from the bowel.
- ✓ Change your sanitary protection regularly.
- ✗ Try to avoid wearing tights, nylon knickers and close fitting jeans.
- ✗ Try to avoid washing with perfumed soaps or using vaginal deodorants.

✗ Do not wash or rub yourself hard with sponges or flannels and avoid hot baths with strong perfumed oils.

If you are still worried or have any questions about the symptoms or the treatment of thrush, do not hesitate to ask your doctor or pharmacist for advice.

This leaflet was last revised in xxx 2021.

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