



Canesten

Active Substance: Clotrimazole
6-Day Treatment Vaginal Tablets

100 mg, Vaginal Tablets
[6-day]

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What Canesten (6-Day Treatment Vaginal Tablets) are and what they are used for
2. What you need to know before you use Canesten (6-Day Treatment Vaginal Tablets)
3. How to use Canesten (6-Day Treatment Vaginal Tablets)
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6. Contents of the pack and other information

1. WHAT *Canesten (6-Day Treatment Vaginal Tablets)* ARE AND WHAT THEY ARE USED FOR

Canesten (6-Day Treatment Vaginal Tablets) are a medicine for the treatment of vaginal thrush (vaginal candidiasis).

The active substance clotrimazole inhibits the growth and proliferation of fungal cells such as yeasts and a number of other fungi as well as some bacteria.

***Canesten (6-Day Treatment Vaginal Tablets)* are used for:**

Infectious discharge caused by yeasts; vaginitis caused by fungi, usually yeasts of the genus *Candida*; superinfections due to clotrimazole-susceptible bacteria.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE *Canesten (6-Day Treatment Vaginal Tablets)*

Do not use *Canesten (6-Day Treatment Vaginal Tablets)* if you are allergic to clotrimazole or any of the other ingredients of *Canesten (6-Day Treatment Vaginal Tablets)* listed in section 6.

Special care is required when using *Canesten (6-Day Treatment Vaginal Tablets)*:

If any of the following applies, you should use this medicine only under certain conditions and only with special care.

Consult a doctor if you suffer from fever (temperature of 38°C or higher), abdominal pain, back pain, foul-smelling vaginal discharge, nausea, vaginal bleeding and/or accompanying shoulder pain.

Please talk to your doctor

- if this is the first time you have had these symptoms;
- if you have had more than four such fungal infections in the past 12 months.

Use of *Canesten (6-Day Treatment Vaginal Tablets)* with other medicines

Tell your doctor or pharmacist if you are taking or have recently taken or intend to take any other medicines, including those obtained without a prescription.

Simultaneous use of vaginally administered clotrimazole and oral tacrolimus (FK-506 immunosuppressant) can result in increased plasma tacrolimus and sirolimus levels. Patients should therefore be monitored closely for symptoms of tacrolimus or sirolimus overdose, if necessary by determining the plasma concentration level of these drugs.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, ask your doctor for advice before using *Canesten (6-Day Treatment*

Vaginal Tablets).

You can use *Canesten (6-Day Treatment Vaginal Tablets)* during pregnancy and breast-feeding, but only on a doctor's instructions.

No studies are available on the influence of clotrimazole on fertility in humans.

Driving and using machines

Canesten (6-Day Treatment Vaginal Tablets) have no influence on the ability to drive and use machines.

Important information about certain other ingredients of *Canesten (6-Day Treatment Vaginal Tablets)*

Note

If the vaginal tablet is **used simultaneously with latex products** (e.g. condoms, diaphragms), the excipients (in particular stearates) may impair the function of those products and therefore adversely affect their reliability.

The effect is temporary and occurs only during treatment.

3. HOW TO USE *Canesten (6-Day Treatment Vaginal Tablets)*

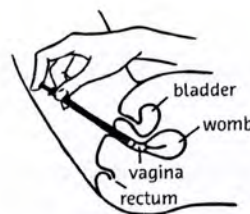
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by your doctor, the recommended dose is:

Insert one tablet as high as possible into the vagina once daily in the evening on six consecutive days as described below.

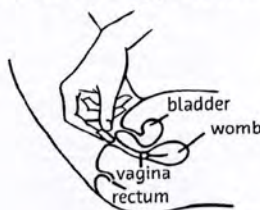
Use with the applicator

1. Pull out the applicator plunger until it stops. Place the vaginal tablet in the applicator so that its rounded end protrudes about halfway out of the applicator. Squeeze the round tip of the applicator at both sides with your fingers.
2. Gently push the applicator with the vaginal tablet as deeply as possible into your vagina (best done while lying on your back).
3. Slowly push the plunger until it stops. This places the vaginal tablet in your vagina. Remove the applicator.
4. After use, wash the applicator carefully in warm (not boiling) water.



Use without the applicator

You can also use the vaginal tablet without the applicator.



Treatment should **not be carried out during menstruation** and should be completed before it begins.

Note

The vaginal tablet may not dissolve completely if the vagina is dry. You may then notice pieces of undissolved vaginal tablet expelled from the vagina, for example in your underwear.

Duration of use

Use on six consecutive days is generally sufficient to eliminate a fungal infection. If necessary, however, the treatment can be repeated.

Generally the symptoms of vaginal inflammation, especially if it is caused by fungi (e.g. itching,

Storage conditions

Do not store above 30°C.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Canesten (6-Day Treatment Vaginal Tablets) contain**

The active substance is: clotrimazole. One vaginal tablet contains 100 mg clotrimazole.

The other ingredients are: calcium lactate pentahydrate, crospovidone, highly dispersed silicon dioxide, lactose monohydrate, magnesium stearate (Ph. Eur.), maize starch, methyl hydroxypropyl cellulose, microcrystalline cellulose, lactic acid.

What Canesten (6-Day Treatment Vaginal Tablets) look like and contents of the pack

Canesten (6-Day Treatment Vaginal Tablets) are white, oblong vaginal tablets. The package contains one aluminium blister pack with six vaginal tablets and a separate applicator.

Manufactured by

Bayer Pharma AG,
Leverkusen, Germany.

for

Bayer Consumer Care AG,
Basel, Switzerland.

This leaflet was last revised in July, 2013.