

## PATIENT INFORMATION LEAFLET

**Read all of this leaflet carefully because it contains important information for you**

This medicine is available without a doctor's prescription, for you to treat a fungal infection. Nevertheless you still need to use Canesten 1 Vaginal Tablet carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days or if symptoms have not disappeared in 7 days.

**SCHEDULING STATUS:** S1

**PROPRIETARY NAME (AND DOSAGE FORM):**



**Canesten® 1**

Vaginal Tablet

### **WHAT CANESTEN 1 VAGINAL TABLET CONTAINS:**

Active ingredient is: clotrimazole 500 mg

The other ingredients are : Lactose monohydrate, Cellulose, microcrystalline, Maize starch, Crospovidone, Magnesium stearate, Lactic acid, Silica, colloidal anhydrous, Calcium lactate pentahydrate, Hypromellose 15 mPs/s

### **WHAT CANESTEN® 1 VAGINAL TABLET IS USED FOR:**

#### **Pharmacotherapeutic group**

Antifungals

#### **Therapeutic indication**

Canesten® 1 Vaginal Tablet is used for the treatment of fungal infections of the vagina.

Clotrimazole the active ingredient in Canesten® 1 Vaginal tablet inhibits the growth and multiplication of fungal cells such as yeasts, a number of fungi and some bacteria.

### **BEFORE YOU TAKE CANESTEN® 1 VAGINAL TABLET:**

- Do not use in girls under 12 years of age, except on the advice of a medical practitioner
- Canesten® 1 vaginal tablet may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment.
- Do not use Canesten® 1 Vaginal Tablet if you are hypersensitive to clotrimazole or any of the other ingredients.

**Special Warnings:**

- Not for oral use.
- Use only if you have already had a vaginal yeast infection diagnosed by a medical practitioner and you have the same symptoms now, otherwise consult your doctor. These symptoms include itching and burning of the vagina and sometimes a white discharge.
- If there is no improvement in 3 days or if symptoms have not disappeared in 7 days, then consult a medical practitioner as not all vaginal infections are caused by yeasts.
- Consult a medical practitioner if you have abdominal pain, fever or a foul-smelling vaginal discharge before or during the use of this medication.
- If symptoms recur within 2 months, consult a medical practitioner.
- If skin rash or new irritation occurs, discontinue use.

**Pregnancy and Breast feeding**

Canesten® 1 Vaginal Tablet should not be used in the first 3 months of pregnancy except on the advice of a medical practitioner.

During pregnancy the Canesten® 1 Vaginal Tablet 500 mg should be inserted without using an applicator.

**Interaction with other medicinal products**

Not known.

**HOW TO TAKE CANESTEN® 1 VAGINAL TABLET**

CANESTEN®1 Vaginal Tablet should be inserted, preferably at night, into the vagina as deeply as possible (see instructions for use of applicator). This is best achieved when lying back with the legs slightly drawn up. If necessary, a second treatment may be carried out.

It is recommended that the treatment should be timed so as to avoid the menstrual period. For prevention of re-infection the partner should be treated locally with clotrimazole cream at the same time, in as far as symptoms (e.g. pruritus, inflammation, etc.) are present.

**In individual cases where disintegration of the tablet does not occur, such as in dry vagina associated with menopause, it is recommended that clotrimazole vaginal cream be used.**

During pregnancy the vaginal tablets should be used and should be inserted without the applicator.

**POSSIBLE SIDE EFFECTS:**

- Local reactions including irritation and burning may occur. Contact allergic dermatitis has been reported.
- In the case of systemic absorption, lower abdominal cramps, increase in urinary frequency or skin rash may occur.
- In isolated cases there may be generalised hypersensitivity reactions of varying degrees of severity. These reactions may affect the skin (e.g. itching, redness), breathing (shortness of breath), the circulation (e.g. a drop in blood pressure requiring treatment or even impaired consciousness) or the gastrointestinal tract (e.g. nausea, diarrhoea).
- Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

**STORING AND DISPOSING OF CANESTEN® 1 VAGINAL TABLET:**

Keep all medicines out of the reach of children.

Store below 25°C.

Do not use after the expiry date on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

**PRESENTATION OF CANESTEN® 1 VAGINAL TABLET:**

Pack containing one vaginal tablet of 500 mg with applicator.

**IDENTIFICATION OF CANESTEN® 1 VAGINAL TABLET:**

White oblong vaginal tablet with the word Bayer on one side and MU on the other side.

**REGISTRATION NUMBER:** Q/20.2.2/281

**NAME AND ADDRESS OF THE REGISTRATION HOLDER:**

Bayer (Pty) Ltd

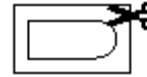
27 Wrench Road, Isando, 1600

Reg No 1968/011192/07

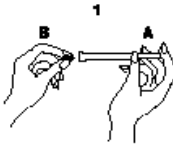
**DATE OF PUBLICATION OF THIS PACKAGE INSERT :** April 1995

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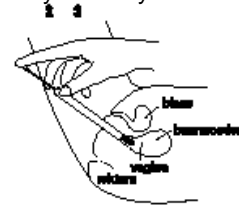
Prior to application remove one tablet from the aluminium foil



**Directions for using the Applicator :**



1. Pull out plunger A until it stops. Place a vaginal tablet into the applicator B.
2. Insert applicator containing the tablet carefully and as deeply as possible into vagina (preferably lying on your back). Push plunger A until it stops, thereby depositing the tablet into the vagina.  
Remove the applicator.
3. After use, remove plunger A completely by pulling it out of applicator B.
4. Then wash it in warm (not boiling) soapy water, rinse and dry carefully.



**Important Notice :**

The product may be used during pregnancy when prescribed by a doctor. Pregnant women should follow the instructions of their doctor strictly. During pregnancy, insertion of the tablet should be done without using the applicator.

ZIMBABWE: PIM 88/14.17/1934

TANZANIA: TAN 00.973 DO1A BAY

BOTSWANA: BOT0500737

NAMIBIA: NS1 90/20.2.2/00357

Manufactured by Bayer AG, Germany