

**a) Package insert Human Medicine**

*The under-mentioned information with regard to this medicine shall appear on the package insert. The information shall be presented in the format stipulated, provided that the Council may authorise any deviation from such information or such format (refer to Regulation 9 of the Act).*

- 1      Scheduling status
- 2      Proprietary name and dosage form
- 3      Composition
- 4      Pharmacological classification
- 5      Pharmacological action  
        Pharmacodynamics properties  
        Pharmacokinetics properties
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- 7      Contra-indications
- 8      Warnings
- 9      Interactions
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- 18     Name and business address of the holder of the certificate of registration
- 19     Date of publication of the package insert

**SCHEDULING STATUS :** S1

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



**Canesten®**

Vaginal Tablets

**COMPOSITION :**

Each vaginal tablet contains clotrimazole 100 mg

**PHARMACOLOGICAL CLASSIFICATION :** A 20.2.2. Fungicides

**PHARMACOLOGICAL ACTION :**

Clotrimazole is a broad spectrum antimycotic with fungicidal properties.

**INDICATIONS :**

For the relief of vaginal itching, burning and discharge associated with recurrent vaginal yeast infections (vaginal candidiasis).

**CONTRA-INDICATIONS :**

Possible hypersensitivity to clotrimazole.

**WARNINGS :**

- i) Not for oral use.
- ii) 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.

- iii) If there is no improvement in 3 days or if symptoms have not disappeared within 7 days, then consult a medical practitioner as not all vaginal infections are caused by yeasts.
- iv) Consult a medical practitioner if you have abdominal pain, fever or a foul-smelling vaginal discharge before or during use of this medication.
- v) If symptoms recur within 2 months, consult a medical practitioner.
- vi) If you are pregnant or think you may be pregnant or are nursing, do not use this medication except on the advice of a medical practitioner.
- vii) Do not use in girls under 12 years of age, except on the advice of a medical practitioner.
- viii) If skin rash or new irritation occurs, discontinue use.
- ix) Canesten® Vaginal Tablets may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment.

#### **DOSAGE AND DIRECTIONS FOR USE :**

##### First infections :

In general, a 3-day treatment for Candida vaginitis will be sufficient. On three consecutive nights, 2 CANESTEN Vaginal Tablets are inserted as deeply as possible into the vagina (see directions for use of applicator). This is best achieved when lying down with the knees slightly bent.

##### Re-infections :

In general a 6-day treatment will be sufficient. On six consecutive nights, one CANESTEN Vaginal Tablet is inserted as deeply as possible into the vagina even if symptoms disappear. If individual cases should require it, two vaginal tablets can be used daily, i.e. one in the morning and one in the evening for 6 - 12 days. Use even during menstruation, although it is recommended that the treatment should be timed so as to avoid the menstrual period and be finished before the onset of menstruation. For prevention of re-infection, the partner should be treated locally with clotrimazole cream at the same time. CANESTEN Vaginal Tablets are odourless, colourless and do not stain the underwear.

**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.**

**SIDE EFFECTS AND SPECIAL PRECAUTIONS :**

Local reactions including irritating and burning may occur. Contact allergic dermatitis has been reported. In cases of systemic absorption, lower abdominal cramps, increase in urinary frequency or skin rash may occur. CANESTEN Vaginal Tablets should not be administered to pregnant women during the first trimester, since the safety in this regard has not been established. During pregnancy, the CANESTEN Vaginal Tablets should be inserted without using an applicator. CANESTEN Vaginal Tablets may only be used during pregnancy on the advice of a medical doctor. The possibility of absorption of clotrimazole when administered vaginally cannot be excluded.

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).

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT :**

Gastro-intestinal disturbances and central nervous system depression may follow accidental oral ingestion. Treatment is symptomatic and supportive.

**IDENTIFICATION :**

White, oblong vaginal tablets with P3 on one side, and Bayer on the other side.

**PRESENTATION :**

Pack containing 6 vaginal tablets of 100 mg each, sealed in aluminium foil, with applicator.

**STORAGE INSTRUCTIONS :**

Store below 25° C. Keep out of reach of children.

**REGISTRATION NUMBER :** E/20.2.2/47

**NAME AND BUSINESS ADDRESS OF THE APPLICANT :**

Bayer (Pty) Ltd

Wrench Road Isando 1600

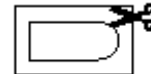
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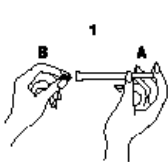
**DATE OF PUBLICATION OF THIS PACKAGE INSERT :** April 1995

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Prior to application remove one tablet from the aluminium foil (as illustrated).



**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 the vagina (preferably lying on your back).

3. Push plunger A until it stops, thereby depositing the tablet into the vagina. Then remove the applicator.

4. After use, remove plunger A completely by pulling it out of applicator B. Then wash it in warm (not boiling) soapy water, rinse and dry carefully.



**Important Notice :**

The product may only 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.

Manufactured by Bayer AG, Germany