

**b) Patient information leaflet**

*The under-mentioned information with regard to this medicine shall appear on the patient information leaflet. 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 10 of the Act).*

- 1 Scheduling status
- 2 Proprietary name and dosage form
- 3 Composition of the medicine, that is, what this medicine contains
- 4 Approved indication and use, that is, what this medicine is used for
- 5 Instruction before using the medicine
- 6 Instructions on how to use the medicine
- 7 Side effects
- 8 Storage and disposal information
- 9 Presentation
- 10 Identification
- 11 Registration number
- 12 Name and business address of the holder of the certificate of registration
- 13 Date of publication of the Patient Information Leaflet.

**SCHEDULING STATUS:** S1

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:**



**CANESTEN®**  
Vaginal Tablets 100 mg

**WHAT CANESTEN® VAGINAL TABLETS CONTAINS:**

**The active ingredient is:** Clotrimazole 100 mg

**The other ingredients are:** Calcium lactate pentahydrate, cellulose microcrystalline, crospovidone, hypromellose 15 cP, lactic acid, lactose monohydrate, magnesium stearate, maize starch, silica, colloidal anhydrous.

**WHAT CANESTEN® VAGINAL TABLETS ARE USED FOR:**

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

**BEFORE YOU USE CANESTEN® VAGINAL TABLETS:**

**Do not use CANESTEN® Vaginal Tablets:**

- If you are allergic to clotrimazole or any of the other ingredients of CANESTEN® Vaginal Tablet.
- If you are using tampons, intravaginal douches, spermicides or other vaginal preparations while using CANESTEN® Vaginal Tablets.
- If you are under 12 years of age.
- If you are having your menstrual period.

**Take special care with CANESTEN® Vaginal Tablets:**

- If you have a fever, lower abdominal pain, back pain, foul smelling vaginal discharge, nausea, vaginal bleeding, and/or associated shoulder pain.
- Avoid vaginal intercourse as it may result in vaginal infection and while using CANESTEN® Vaginal Tablets your partner could become infected.
- If symptoms persist for more than 7 days the patient may have a medical condition that requires treatment by a doctor.
- CANESTEN® Vaginal Tablets may reduce the effectiveness and safety of latex products such as condoms and diaphragms.

**Pregnancy and Breast feeding:**

You should not use CANESTEN® Vaginal Tablets in the first three (3) months of pregnancy.

Discontinue breast-feeding during treatment with CANESTEN® Vaginal Tablets.

During pregnancy the treatment should be carried out with CANESTEN® Vaginal Tablets, since these can be inserted without using an applicator.

**Driving and using machinery:**

CANESTEN® Vaginal Tablets have no or negligible influence on the ability to drive or use machinery.

**Using other medicines with CANESTEN® Vaginal Tablet:**

The use of CANESTEN® Vaginal Tablets with oral tacrolimus (FK-506; immunosuppressant) might lead to increased tacrolimus plasma levels and similarly with sirolimus. You should thus be thoroughly monitored for symptoms of tacrolimus or sirolimus overdose, if necessary by determination of the respective plasma levels.

**HOW TO USE CANESTEN® VAGINAL TABLETS:**

- You should introduce one (1) CANESTEN® Vaginal Tablet every evening for six (6) successive days.

- Insert CANESTEN® Vaginal Tablet as deeply as possible into the vagina in the evening before going to bed (see instructions for use of applicator).
- Insertion is best achieved when lying back with legs slightly drawn up.

**If you use more CANESTEN® Vaginal Tablets than you should:**

There is no risk of serious harm as it is unlikely to occur following a single vaginal application of an overdose or unintended oral ingestion.

**POSSIBLE SIDE EFFECTS:**

Tell your doctor if you notice any of the following:

- Abnormal low blood pressure
- Hives or skin rash
- Shortness of breath
- Loss of conscious
- Pelvic pain
- Genital peeling
- Itching
- Oedema (swelling)
- Redness of the skin
- Discomfort
- Burning
- Irritation
- Vaginal bleeding
- Abdominal pain.

**STORING AND DISPOSING OF CANESTEN® VAGINAL TABLETS**

Store at or below 25 °C.

**PRESENTATION OF CANESTEN® VAGINAL TABLETS:**

Carton containing six (6) CANESTEN® Vaginal Tablets of 100 mg each, sealed in aluminium foil, with 6 applicators.

**IDENTIFICATION OF CANESTEN® VAGINAL TABLETS:**

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

**REGISTRATION NUMBER:**

E/20.2.2/47

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

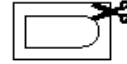
Bayer (Pty) Ltd  
27 Wrench Road, Isando 1600  
South Africa  
Co. Reg No 1968/011192/07

**DATE OF PUBLICATION:**

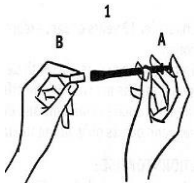
April 1995

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NAMIBIA	90/20.2.200360
BOTSWANA	B9300960

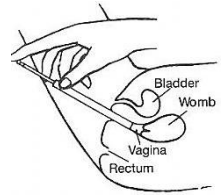
Prior to application remove one tablet from the aluminium foil (as illustrated).



**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 Vagina (preferably lying on your back).
3. Push plunger A until it stops, thereby depositing the tablet into the vagina.
4. Remove the applicator.
5. After use, remove plunger A completely by pulling it out of applicator B.
6. 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.

**Bayer**