Applicant:	**Bayer (Pty) Ltd**
Product proprietary name	**Canesten 1 Vaginal Tablet**
Dosage form and strength	**Vaginal Tablet 500 mg**

SCHEDULING STATUS S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

CANESTEN® 1 VT
Vaginal Tablet 500 mg

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

CANESTEN® 1 Vaginal Tablet is available without a doctor's prescription, for you to treat a mild illness. 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.
- Do not share CANESTEN® 1 Vaginal Tablet with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

WHAT CANESTEN® 1 VAGINAL TABLET CONTAINS

The active ingredient is: Clotrimazole 500 mg

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

WHAT CANESTEN® 1 VAGINAL TABLET IS USED FOR

For the relief of vaginal itching, burning and discharge associated with vaginal yeast infections.

BEFORE YOU USE CANESTEN® 1 VAGINAL TABLET

Do not use CANESTEN® 1 Vaginal Tablet:

- If you are hypersensitive (allergic) to clotrimazole or any of the other ingredients of CANESTEN® 1 Vaginal Tablet.
- If you are below 12 years of age.
- If you are having your menstrual period.

Take special care with CANESTEN® 1 Vaginal Tablet:

- If you have a fever, lower abdominal pain, back pain, foul smelling vaginal discharge, nausea, vaginal haemorrhage, and/or associated shoulder pain, you should consult your doctor.
- Avoid vaginal intercourse while using CANESTEN® 1 Vaginal Tablet as it may result in vaginal infection and your partner could become infected.
- If symptoms persist for more than 7 days you may have a condition that requires medical treatment. You should consult your doctor.
- You should not use tampons, intra-vaginal douches, spermicides or other vaginal products while using CANESTEN® 1 Vaginal Tablet.
- CANESTEN® 1 Vaginal Tablet may reduce the effectiveness and safety of latex products such as condoms and diaphragms. Additional contraceptive measures are required when using CANESTEN® 1 Vaginal Tablet.
- CANESTEN® 1 Vaginal Tablet contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not use CANESTEN® 1 Vaginal Tablet.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before using this medicine.

CANESTEN® 1 Vaginal Tablet should not be used in the first three (3) months of pregnancy.

Breastfeeding should be discontinued during treatment with CANESTEN® 1 Vaginal Tablet.

Driving and using machinery:

CANESTEN® 1 Vaginal Tablet has no or negligible influence on the ability to drive or use machinery.

Using other medicines with CANESTEN® 1 Vaginal Tablet:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

The use of CANESTEN® 1 Vaginal Tablet with oral tacrolimus or sirolimus may lead to increased tacrolimus plasma levels and similarly with sirolimus. You should thus be thoroughly monitored for symptoms of tacrolimus or sirolimus overdosage, if necessary by determination of the respective plasma levels.

HOW TO USE CANESTEN® 1 VAGINAL TABLET

Always use CANESTEN® 1 Vaginal Tablet exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

- Introduce CANESTEN® 1 Vaginal Tablet in the evening before going to bed.
- The CANESTEN® 1 Vaginal Tablet should be inserted as deeply as possible into the vagina using the applicator (see instructions for use of applicator).
- Insertion is best achieved when lying back with legs slightly drawn up.

It is recommended that the treatment with CANESTEN® 1 Vaginal Tablet should be avoided during the menstrual period.

During pregnancy the vaginal tablet should not be inserted with the applicator.

If you use more CANESTEN® 1 Vaginal Tablet than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital of poison control centre.

In case of unintended oral ingestion, stomach pain, loss of consciousness and shortness of breath may occur. Treatment is symptomatic and supportive.

POSSIBLE SIDE EFFECTS

CANESTEN® 1 Vaginal Tablet can have side effects.

Not all side effects reported for CANESTEN® 1 Vaginal Tablet are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking CANESTEN® 1 Vaginal Tablet and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hives or skin rash
- Temporary loss of consciousness – (this is as a result of an allergic reaction to the ingredients of CANESTEN® 1 Vaginal Tablet)
- Itching
- Vaginal oedema (swelling)

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CANESTEN® 1 Vaginal Tablet. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Pelvic pain
- Shortness of breath
- Vaginal bleeding

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Abnormal low blood pressure – (symptoms are dizziness/light headedness, fainting, feeling sick)
- Genital peeling – (this is as a result of the exfoliation process of removing the damaged vaginal epithelium)
- Redness of the skin
- Discomfort
- Burning
- Irritation
- Abdominal pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF CANESTEN® 1 VAGINAL TABLET

Store all medicines out of reach of children.

Store at or below 30 °C.

Protect from light.

Do not use after the expiry date on the carton and blister.

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

Carton containing one (1) CANESTEN® 1 Vaginal Tablet of 500 mg with an applicator.

IDENTIFICATION OF CANESTEN® 1 VAGINAL TABLET

White oblong CANESTEN® 1 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

South Africa

Co. Reg No 1968/011192/07

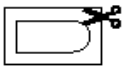
DATE OF PUBLICATION OF THIS PACKAGE INSERT

The following dates should be included:

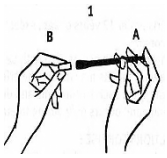
- the date on the registration certificate of the medicine: 23 February 1984
- thereafter the date of the most recently revised package insert as approved by Council: April 1995.

Applicant:	**Bayer (Pty) Ltd**
Product proprietary name	**Canesten 1 Vaginal Tablet**
Dosage form and strength	**Vaginal Tablet 500 mg**

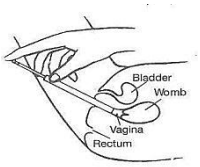
Prior to application remove one tablet from the aluminium foil (as illustrated).



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, the tablet should be inserted without the applicator.

Manufactured for Bayer (Pty) Ltd. by:
Bayer AG 51368 Leverkusen, Germany
GP Grenzach Produktions GmbH Emil-Barell-Str. 7, 79639 Grenzach-Wyhlen, Germany

BOTSWANA	BOT0500737
NAMIBIA	NS1 90/20.2.2/00357
NIGERIA	NAFDAC Reg. No: B4-8043
TANZANIA	TAN 00,973 D01A BAY
ZIMBABWE	PIM 88/14.17/1934