SCHEDULING STATUS: S1

PROPRIETARY NAME AND DOSAGE FORM:

CANESTEN® 1 VT
Vaginal Tablet

COMPOSITION:

The active ingredient is: Clotrimazole 500 mg

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

Contains sugar (lactose)

PHARMACOLOGICAL CLASSIFICATION:

A 20.2.2. Fungicides

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

- Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.
- Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts and moulds.

Pharmacokinetic properties

A pharmacokinetic investigation after vaginal application reported that 3 – 10 % of clotrimazole is absorbed.

INDICATIONS:

Infections of the genital region (vaginitis) caused by Candida.

CONTRAINDICATIONS:

Hypersensitivity to clotrimazole or to any of the excipients of CANESTEN® 1 Vaginal Tablet.

WARNINGS and SPECIAL PRECAUTIONS:

- Keep medicine out of reach of children
- If symptoms persist for more than 7 days the patient should be evaluated by a medical practitioner.
- Recurrent infections may indicate an underlying medical cause. Patient should seek medical advice if symptoms return within 2 months.
- If the labia and adjacent areas are simultaneously infected, local treatment with an external cream should also be given in addition to the intravaginal treatment.
- Treatment during the menstrual period should not be performed. The treatment should be completed before the onset of menstruation.
- Tampons, intravaginal douches, spermicides or other vaginal preparations should not be used while treatment with CANESTEN® 1 Vaginal Tablet is taking place.
- During pregnancy the CANESTEN® 1 Vaginal Tablet should be inserted without using an applicator.
- CANESTEN® 1 Vaginal Tablet is intended for use by women and girls 12 years of age and older only.

Special Precautions:

- Contact with eyes should be avoided.
- CANESTEN® 1 Vaginal Tablet is not for oral use.
- Vaginal intercourse should be avoided in case of vaginal infection and while using CANESTEN® 1 Vaginal Tablet as the partner could become infected.
- 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.

- Contains lactose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactasedeficiency, glucose-galactose malabsorptio or fructose intolerance should not use CANESTEN® 1 Vaginal Tablet[1].

Effects on ability to drive and use machines:

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

INTERACTIONS:

Concomitant medication with CANESTEN® 1 Vaginal Tablet and oral tacrolimus (FK-506; immunosuppressant) may lead to increased tacrolimus plasma levels and similarly with sirolimus. Patients should thus be thoroughly monitored for symptoms of tacrolimus or sirolimus overdosage, if necessary by determination of the respective plasma levels.

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

Pregnancy:

There is limited amount of data from the use of CANESTEN® 1 Vaginal Tablet in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of CANESTEN® 1 Vaginal Tablet during the first trimester of pregnancy

During pregnancy CANESTEN® 1 Vaginal Tablet should be inserted without an applicator.

Lactation:

Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/ metabolites in milk. Breastfeeding should be discontinued during treatment with CANESTEN® 1 Vaginal Tablet.

DOSAGE AND DIRECTIONS FOR USE:

CANESTEN® 1 Vaginal Tablet should be inserted 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 the legs slightly drawn up.

CANESTEN® 1 Vaginal Tablet needs moisture in the vagina to dissolve completely, otherwise non-dissolved pieces of the vaginal tablet might crumble out of the vagina. To prevent this, it is important to insert the medication as deeply as possible into the vagina at bedtime. Should the CANESTEN® 1 Vaginal Tablet not dissolve completely within one night, the use of a vaginal cream should be considered.

SIDE EFFECTS:

The following adverse reactions have been identified during post-approval use of CANESTEN® 1 Vaginal Tablet. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to estimate their frequency.

Immune system disorders:

Allergic reaction (syncope, hypotension, dyspnoea, urticaria).

Gastrointestinal disorders:

Abdominal pain.

Reproductive system and breast disorders:

Genital peeling, - (this is a result of the natural exfoliation process of removing damaged vaginal epithelium), pruritus, rash, oedema, erythema, discomfort, burning, irritation, pelvic pain, vaginal haemorrhage.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

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

IDENTIFICATION:

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

PRESENTATION:

CANESTEN® 1 Vaginal Tablet of 500 mg sealed in aluminium foil, with an applicator into a carton.

STORAGE INSTRUCTIONS:

Store at or below 30 °C. Keep out of the reach of children.

REGISTRATION NUMBER:

Q/20.2.2/281

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Bayer (Pty) Ltd

27 Wrench Road, Isando 1600

South Africa

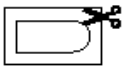
Co.Reg No 1968/011192/07

DATE OF PUBLICATION OF THE PACKAGE INSERT:

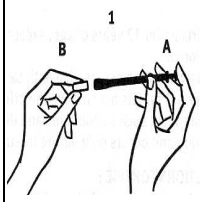
The following dates should be included:

- 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.

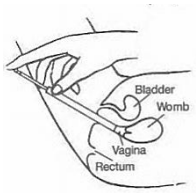
Prior to application remove one tablet from the aluminium foil (as illustrated).



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:
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