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 387 – 395 mg/tablet

CATEGORY AND CLASS:

A 20.2.2. Fungicides

PHARMACOLOGICAL ACTION:

Clotrimazole has a fungicidal action on *Candida* species.

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 AND SPECIAL PRECAUTIONS:

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 in 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 the 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®1 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:

In general, a single dose treatment will be sufficient for Candida vaginitis. The 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.

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. CANESTEN 1 Vaginal Tablet 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 1 Vaginal Tablet 500 mg should be inserted without using an applicator. CANESTEN 1 Vaginal Tablet 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:

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:

Pack containing one vaginal tablet of 500 mg with applicator.

STORAGE INSTRUCTIONS:

Store at or below 25°C. Keep out of 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

Co. Reg. No 1968/011192/07

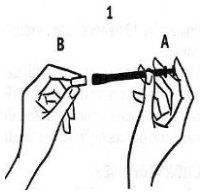
DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

April 1995

Bayer

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

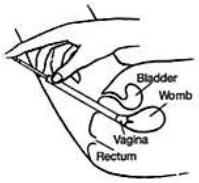
Directions for using the Applicator:



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. 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 theirdoctor strictly. During pregnancy, insertion of the tablet should be done without using the applicator.

ZIMBABWE: PID88/14.17/1934

TANZANIA: TAN 00,973 DO1A BAY

Manufactured and packed by Bayer AG, Germany.