PROFESSIONAL INFORMATION

SCHEDULING STATUS: S1

PROPRIETARY NAME AND DOSAGE FORM: **Canesten® 3VC**
Vaginal Cream

COMPOSITION:

Active ingredient: Clotrimazole 20 mg

Preservative: Benzyl alcohol 1 % m/m

Inactives: 2-Octylodecanol

cetyl esters wax

cetylstearyl alcohol

sorbitan monostearate

polysorbate 60

Inert ointment base o/w to 1 g.

CATEGORY AND CLASS:

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 and / or cetostearyl alcohol.

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WARNINGS and SPECIAL PRECAUTIONS:

i. 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.

ii. 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.

iii. Consult a medical practitioner if you have abdominal pain, fever or a foul-smelling, or a vaginal discharge before or during use of this medication.

iv. If symptoms recur within 2 months, consult a medical practitioner.

v. Do not use in girls under 12 years of age, except on the advice of a medical practitioner.

vi. If skin rash or new irritation occurs, discontinue use.

vii. Direct contact with Canesten Vaginal Cream may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment.

HUMAN REPRODUCTION:

Safety has not been established.

CANESTEN Vaginal Cream may only be used during pregnancy on the advice of a medical doctor. CANESTEN Vaginal Cream should not be administered to pregnant women during the first trimester, since the safety in this regard has not been established. The possibility of absorption of clotrimazole when administered vaginally cannot be excluded.

DOSAGE AND DIRECTIONS FOR USE:

Fill enclosed vaginal applicator to the top (i.e. 5 g CANESTEN 3VC). Insert deeply into the vagina every night on retiring for three consecutive days even if symptoms disappear.

This is best achieved when lying on the back with the legs pulled in a little towards the body.

If individual cases should require it, two applications of 5 g Canesten 3VC 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 not be carried out during menstruation but should be completed before

menstruation begins. For candida vulvitis or vulvo-vaginitis the vaginal cream should be applied thinly to the external genitalia 2 or 3 times a day for 1 - 2 weeks. For the prevention of re-infection, the partner should be treated locally with CANESTEN Cream at the same time in so far as symptoms (e.g. pruritus, inflammation, etc.) are present. CANESTEN preparations are colourless and do not stain the underwear.

SIDE EFFECTS:

Skin and appendages: burning, pruritus, and rash. Contact allergic dermatitis has been reported.

Body as a whole: allergic reaction (syncope, hypotension, dyspnoea, gastrointestinal disorders), pain.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:

See side-effects and special precautions. In case of accidental ingestion, gastro-intestinal disturbances and central nervous system depression may occur. Treatment is symptomatic and supportive.

IDENTIFICATION: A soft, white cream.

PRESENTATION: Aluminium tube of 20 g closed with a polyethylene screw cap and 3 vaginal applicators.
Aluminium tube of 30 g closed with a polyethylene screw cap and 3 vaginal applicators.

STORAGE INSTRUCTIONS:

Store at or below 25 ^{o}C. Keep out of reach of children.

REGISTRATION NUMBER: A39/20.2.2/0589

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

PROFESSIONAL INFORMATION

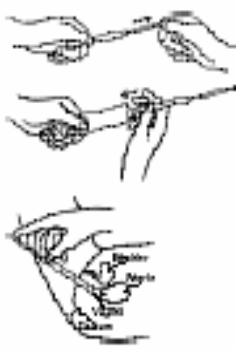
DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

Date on the registration certificate of the medicine: 26 October 2012

Date of the most recently revised professional information as approved by Council: 26 October 2012

Bayer

DIRECTIONS FOR USING THE APPLICATOR:



1. Wash your hands thoroughly.
2. Pull out plunger of disposable applicator until it stops.
3. Open tube. Attach disposable applicator to tube, hold it firmly pressed against tube and fill it by squeezing tube carefully.
4. Detach applicator from the tube, insert as deeply as possible into the vagina (best achieved when lying on your back) and empty by pressing the plunger.
5. Remove applicator and dispose of it.

Each applicator is for use once only.
The surplus cream in the 20g or 30g tube of CANESTEN 3VC may be used to treat any inflammation of the vulva (outer vaginal area) and nearby areas. The cream should be applied thinly and rubbed in gently 2 - 3 times a day. Follow your doctor's instructions.

NB! In case of hypersensitivity to cetylstearyl alcohol, CANESTEN Vaginal Tablets should be used for the treatment.

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