Bayer HealthCare

PATIENT INFORMATION LEAFLET

Product Proprietary Name: CANESTEN® 3 VC 2 % Vaginal Cream

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SCHEDULING STATUS: S1

CANESTEN® 3VC

Clotrimazole 20 mg/g

Read all of this leaflet carefully because it contains important information for you
CANESTEN® 3VC is available without a doctor's prescription, for you to treat a fungal infection. Nevertheless, you still need to use CANESTEN® 3VC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CANESTEN® 3VC with another person, even if their symptoms are the same as yours.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days or if symptoms have not disappeared in 7 days

What is in this leaflet

1. What CANESTEN® 3VC is and what it is used for
2. What you need to know before you use CANESTEN® 3VC
3. How to use CANESTEN® 3VC
4. Possible side effects
5. How to store CANESTEN® 3VC
6. Contents of the pack and other information

1. What CANESTEN® 3VC is and what it is used for

Antifungals

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

2. What you need to know before you use CANESTEN® 3VC

Do not use **CANESTEN® 3VC:**

- if you are hypersensitive (allergic) to clotrimazole or any of the other ingredients of CANESTEN® 3VC (listed in section 6).
- If you are a girl under 12 years of age, except on the advice of a medical practitioner.

Warnings and precautions

Take special care with CANESTEN® 3VC :

Not for oral use.

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

If symptoms recur within 2 months, consult a medical practitioner.
If skin rash or new irritation occurs, discontinue use.
CANESTEN® 3VC may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment.

Other medicines and CANESTEN® 3VC

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

There are no known interactions between CANESTEN® 3VC and other medicines.

Pregnancy and Breastfeeding

CANESTEN® 3VC should not be used in the first 3 months of pregnancy except on the advice of a medical practitioner. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using this medicine.

Driving and using machines

CANESTEN® 3VC has no or negligible influence on the ability to drive or use machinery

3. How to use CANESTEN® 3VC

- Always use CANESTEN® 3VC exactly as described in this leaflet or as your doctor, or pharmacist has told you. Check with your doctor or, pharmacist or if you are not sure.
- 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 this 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® 3 VC 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.

4. Possible side effects

CANESTEN® 3VC can have side effects.

Not all side effects reported for CANESTEN® 3VC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using CANESTEN® 3VC , please consult your doctor, pharmacist or other healthcare professional for advice.

Local reactions including skin irritation and burning may occur.
Contact allergic dermatitis has been reported.
In cases of systemic absorption, lower abdominal cramps, increase in urinary frequency or skin rash may occur.

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

Reporting of side effects
If you get side effects, talk to your doctor or, pharmacist . You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **CANESTEN® 3VC**.

5. How to store CANESTEN® 3VC

- Store all medicines out of reach of children.
- Store at or below 25°C.
- Do not use after the expiry date on the tube and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What CANESTEN® 3VC contains

- The active substance is: Clotrimazole 20 mg/g
- The other ingredients are: 2-Octylodecanol, cetyl esters wax, cetylstearyl alcohol, benzyl alcohol 2 %, sorbitan monostearate, polysorbate 60, purified water

What CANESTEN® 3VC looks like and contents of the pack

A soft, white cream
Aluminium tube of 20 g or 30 g closed with a polyethylene screw cap and 3 vaginal applicators.

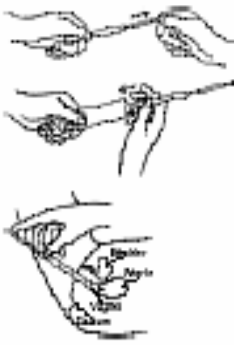
Holder of Certificate of Registration
Bayer (Pty) Ltd
27 Wrench Road, Isando, 1600
Reg No 1968/011192/07

This leaflet was last revised in
26 October 2012

Registration number
A39/20.2.2/0589

Access to the corresponding Professional Information
www.bayer.co.za
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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 ir 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.

Manufactured By: