

PATIENT INFORMATION LEAFLET

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.

Ask your 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.

Do not share Canesten® 3VC with another person, even if their symptoms are the same as yours.

SCHEDULING STATUS: S1

PROPRIETARY NAME (AND DOSAGE FORM):  **Canesten® 3VC**

WHAT CANESTEN® 3VC CONTAINS:

Active ingredient is: Clotrimazole 20 mg/g

The other ingredients are : 2-Octylodecanol, cetyl esters wax, cetylstearyl alcohol, benzyl alcohol, sorbitan monostearate, polysorbate 60, purified water

WHAT CANESTEN® 3VC IS USED FOR:

Antifungals

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

BEFORE YOU USE CANESTEN® 3VC:

Do not use Canesten® 3VC if:

You are a girl under 12 years of age, except on the advice of a medical practitioner.

You are hypersensitive to clotrimazole or cetostearyl alcohol.

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.

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.

Using other medicines with Canesten® 3VC:

Always tell your healthcare professional if you are taking any other medicine.

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

HOW TO USE CANESTEN® 3VC:

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 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® 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.

POSSIBLE SIDE EFFECTS:

Canesten® 3VC can have side effects.

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.

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 this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

STORING AND DISPOSING OF CANESTEN® 3VC:

Keep all medicines out of the reach and sight 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)

IDENTIFICATION OF CANESTEN® VAGINAL CREAM: A soft, white cream

REGISTRATION NUMBER: A39/20.2.2/0589

NAME AND ADDRESS OF THE REGISTRATION HOLDER:

Bayer (Pty) Ltd

27 Wrench Road, Isando, 1600

Reg No 1968/011192/07

DATE OF PUBLICATION:

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