PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

CANESTEN® 1 VC

Vaginal Cream 10 %

Read all of this leaflet carefully because it contains important information for you

CANESTEN® 1 VC is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use CANESTEN® 1 VC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CANESTEN® 1 VC with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

WHAT CANESTEN® 1 VC CONTAINS

- The active substance is Clotrimazole 500 mg/5 g
- The other ingredients are benzyl alcohol 1 % (as a preservative), cetostearyl alcohol, cetyl palmitate, isopropyl myristate, polysorbate 60, sorbitan monostearate and purified water.

WHAT CANESTEN® 1 VC IS USED FOR

For the relief of vaginal itching, burning, discharge and possibly pain associated with vaginal yeast infections (vaginal thrush).

BEFORE USING CANESTEN® 1 VC

Do not use CANESTEN® 1 VC:

- If you are allergic to clotrimazole or to any of the ingredients in CANESTEN® 1 VC
- If you are under 12 years of age
- If you are having your menstrual period.

Take special care with CANESTEN® 1 VC:

- If you have a fever, lower abdominal pain, back pain, foul smelling vaginal discharge, nausea, vaginal bleeding, and/or associated shoulder pain, you should consult your doctor.
- Avoid vaginal intercourse while using CANESTEN® 1 VC as it may result in vaginal infection and your partner could become infected.
- If symptoms persist for more than 7 days you may have a condition that requires medical treatment. You should consult your doctor.
- You should not use tampons, intravaginal douches, spermicides or other vaginal preparations while using CANESTEN® 1 VC.
- CANESTEN® 1 VC may reduce the effectiveness and safety of latex (rubber) products such as condoms and diaphragms (method of contraceptive)
- As Canesten may reduce the effectiveness of condoms and diaphragms, it would be best if you avoid vaginal intercourse during treatment, to prevent the transmission of HIV and sexually transmitted diseases (STD's), until symptoms of the candidiasis infection have resolved.
- Cetostearyl alcohol may cause local skin reactions (e.g. rash).

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Safety in pregnancy and lactation has not been established.

You should not use CANESTEN® 1 VC during pregnancy.

Breastfeeding should be discontinued during treatment with CANESTEN® 1 VC.

Driving and using machinery:

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

Important information about some of the ingredients of CANESTEN® 1 VC:

Cetostearyl alcohol may cause local skin reactions (e.g. rash).

Using other medicines with CANESTEN® 1 VC

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

The use of CANESTEN® 1 VC and oral tacrolimus (FK-506; immunosuppressant) might 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.

HOW TO USE CANESTEN® 1 VC

Always use Canesten® 1 VC exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

- You should insert CANESTEN® 1 VC as deeply as possible into your 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.
- Insert the content of one applicator in the evening. This is a single dose treatment.

If you use more CANESTEN® 1 VC than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

In case of unintended oral ingestion, stomach pain**,** loss of consciousness and shortness of breath may occur. Treatment is symptomatic and supportive.

POSSIBLE SIDE EFFECTS:

CANESTEN® 1 VC can have side effects.

Not all side effects reported for CANESTEN® 1 VC 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.

If any of the following happens, stop using CANESTEN® 1 VC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hives or skin rash
- Temporary loss of consciousness – (this is as a result of an allergic reaction to the ingredients of CANESTEN® 1 VC.)
- Itching
- Vaginal oedema (swelling)

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CANESTEN® 1 VC. You may need urgent a medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Pelvic pain
- Shortness of breath
- Vaginal bleeding

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Abnormal low blood pressure – (symptoms are dizziness/light headedness, fainting and feeling sick.)
- Genital peeling – (this is as a result of the exfoliation process of removing the damaged vaginal epithelium)
- Redness of the skin
- Discomfort
- Burning
- Irritation
- Abdominal pain.

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

PATIENT INFORMATION LEAFLET

STORING AND DISPOSING OF CANESTEN® 1 VC

Store all medicines out of reach of children.

Store at or below 25 ºC.

Protect from light.

Do not use after the expiry date on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewage systems (e.g. toilets).

PRESENTATION OF CANESTEN® 1 VC

An applicator containing 5 g CANESTEN® 1 VC packed into a carton.

IDENTIFICATION OF CANESTEN® 1 VC

Soft, white cream

REGISTRATION NUMBER

U/20.2.2/205

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Bayer (Pty) Ltd

27 Wrench Road

Isando, 1600

Co. Reg. no. 1968/011192/07

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DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

The date on the registration certificate of the medicine: 04 November 1987

The date of the most recently revised patient information leaflet as approved by Council: 12 December 2017

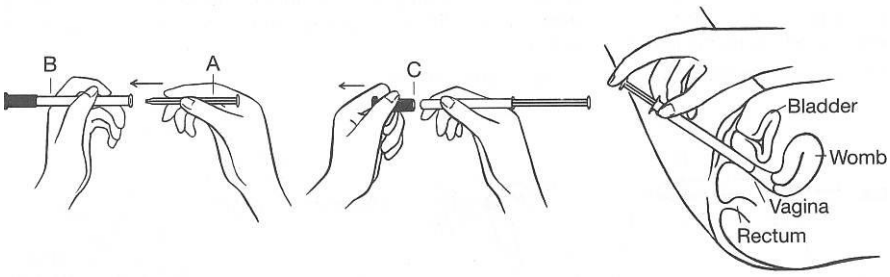
Inserting the applicator:

Slowly push the plunger (A) with the forefinger until it stops.

Remove Cap C.

Carefully insert the end of the applicator (B) **as deeply as possible** into the vagina and then push in plunger A to deposit the cream. This is best achieved when lying on the back with the legs pulled in a little towards the body.

Remove the applicator from the vagina and discard it.



Zimbabwe:	E99/14.17/3632 PIM
Namibia:	NS1 04/20.2.2/0635
Tanzania:	TAN 00,2106 D01A BAY
Botswana:	S3 B9300945

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