

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:



CANESTEN®
Vaginal Cream 1 %

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

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

- Keep this leaflet. You may need to read it again.
- Do not share CANESTEN® Vaginal Cream 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® VAGINAL CREAM CONTAINS:

The active ingredient is: Clotrimazole 10 mg/g

The other ingredients are: benzyl alcohol 2 %, cetostearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, sorbitan monostearate and purified water.

WHAT CANESTEN® VAGINAL CREAM IS USED FOR:

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

BEFORE YOU USE CANESTEN® VAGINAL CREAM:

Do not use CANESTEN® Vaginal Cream

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

Take special care with CANESTEN® Vaginal Cream

- 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 a doctor.
- Avoid vaginal intercourse as it may result in vaginal infection and while using CANESTEN® Vaginal Cream 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.
- CANESTEN® Vaginal Cream may reduce the effectiveness and safety of latex (rubber) products such as condoms and diaphragms (method of contraceptive). You will need to take additional contraceptive measures while using CANESTEN® Vaginal Cream.
- 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.
- You should not use tampons, intra-vaginal douches, spermicides or other vaginal preparations while using CANESTEN® Vaginal Cream.

Pregnancy and Breastfeeding:

- If you are pregnant or breastfeeding your baby while using this medicine, please consult your doctor, pharmacist or other healthcare professional for advice before using this medicine.
- Safety and efficacy of CANESTEN® Vaginal Cream has not been established in pregnancy.
- You should not use CANESTEN® Vaginal Cream during pregnancy.
- Breastfeeding should be discontinued during treatment with CANESTEN® Vaginal Cream.

Driving and using machinery:

CANESTEN® Vaginal Cream has no or negligible influence on the ability to drive or use machinery.

Important information about some of the ingredients of CANESTEN® Vaginal Cream:

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

Using other medicines with CANESTEN® Vaginal Cream:

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

The use of CANESTEN® Vaginal Cream with oral tacrolimus (FK-506; immunosuppressant) might lead to increased tacrolimus plasma levels and similarly with sirolimus. You should thus be thoroughly monitored for symptoms of tacrolimus or sirolimus overdose, if necessary by determination of the respective plasma levels.

HOW TO USE CANESTEN® VAGINAL CREAM:

Always use CANESTEN® Vaginal Cream exactly as your doctor or pharmacist has instructed you.

You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

- You should insert CANESTEN® Vaginal Cream as deeply as possible into the vagina in the evening before going to bed (see instructions for use of the applicator).
- Insertion is best achieved when lying back with legs slightly drawn up.
- Insert the content of one applicator every evening for six (6) successive days.

If you use more CANESTEN® Vaginal Cream than you should:

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

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

If you forget to use a dose of CANESTEN® Vaginal Cream:

Do not use a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:

CANESTEN® Vaginal Cream can have side effects.

Not all side effects reported for CANESTEN® Vaginal Cream are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking CANESTEN® Vaginal Cream 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® Vaginal Cream)
- 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® Vaginal Cream. You may need urgent 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, 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.

STORING AND DISPOSING OF CANESTEN® VAGINAL CREAM:

Store all medicines out of reach of children.

Store at or below 25 °C.

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® VAGINAL CREAM:

- 35 g collapsible aluminium tube of CANESTEN® Vaginal Cream and six (6) applicators placed into an outer carton.
- 50 g collapsible aluminium tube of CANESTEN® Vaginal Cream and six (6) applicators placed into an outer carton.

IDENTIFICATION OF CANESTEN® VAGINAL CREAM:

A soft, white cream.

REGISTRATION NUMBER:

K/20.2.2/187

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

Bayer (Pty) Ltd

27 Wrench Road, Isando, 1600

South Africa

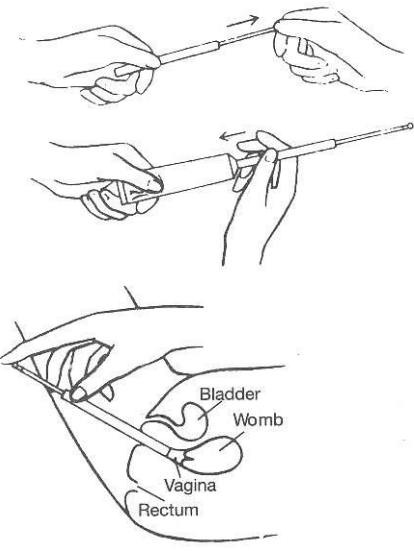
Co. Reg No: 1968/011192/07

Tel. No.: +27 (0) 11 921 5000

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

The date on the registration certificate of the medicine: 27 July 1978

The date of the most recently revised package insert as approved by Council: 20 March 2018



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 35 g or 50 g tube of **CANESTEN® Vaginal Cream** 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 cetostearyl alcohol, **CANESTEN® Vaginal Tablets** should be used for the treatment.

ZIMBABWE	81/14.17/1395 PIM
NAMIBIA	NS1 90/20.2.2/00356
BOTSWANA	S2 BOT0801235

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