PROFESSIONAL INFORMATION

SCHEDULING STATUS: S1

PROPRIETARY NAME AND DOSAGE FORM:

CANESTEN® 1 VC

Vaginal Cream

COMPOSITION:

Active ingredient: Clotrimazole 500 mg/5 g

Inactive ingredients: Benzyl alcohol 1 % (as preservative), cetostearyl alcohol, cetyl palmitate, isopropyl myristate, polysorbate 60, sorbitan monostearate and purified water.

CATEGORY AND CLASS:

A 20.2.2. Fungicides

PHARMACOLOGICAL ACTION:

Pharmacodynamics Properties

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural functional impairment of the fungal cytoplasmic membrane.

Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeast and moulds.

Pharmacokinetic Properties

A pharmacokinetic investigation after vaginal application reported that 3 – 10 % of clotrimazole is absorbed.

INDICATIONS:

Infections of the genital region (vaginitis) caused by Candida.

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CONTRAINDICATIONS:

- Hypersensitivity to clotrimazole or to any of the excipients of CANESTEN® 1 VC (Vaginal Cream).

WARNINGS and SPECIAL PRECAUTIONS:

If symptoms persist for more than 7 days, the patient should be evaluated by a medical practitioner.

Recurrent infections may indicate an underlying medical cause. Patients should seek medical advice if symptoms return within 2 months.

Treatment during the menstrual period should not be performed. The treatment should be completed before the onset of menstruation.

Tampons, intravaginal douches, spermicides or other vaginal products should not be used while using CANESTEN® 1 VC.

Avoidance of vaginal intercourse is recommended in case of vaginal infection and while using CANESTEN® 1 VC as the partner could become infected.

CANESTEN® 1 VC is intended for use by adults and children 12 years of age and older only.

CANESTEN® 1 VC may reduce the effectiveness and safety of latex products such as condoms and diaphragms when applied on the genital area (women: intravaginally, labia and adjacent area of the vulva; men: prepuce and glans of the penis). Additional contraceptive measures are required when using CANESTEN® 1 VC.

As Canesten may reduce the effectiveness of condoms and diaphragms, patients should be advised to refrain from sexual intercourse to prevent transmission of HIV and sexually transmitted diseases (STD's) during treatment until the symptoms of the candidiasis infection have resolved.

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

Special Precautions

Contact with eyes should be avoided.

CANESTEN® 1 VC should not be swallowed.

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Effects on the ability to drive and use machines

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

INTERACTIONS:

Concomitant medication with 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.

HUMAN REPRODUCTION:

Safety in pregnancy and lactation has not been established.

Pregnancy

There is limited amount of data from the use of CANESTEN® 1 VC in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of CANESTEN® 1 VC during the first trimester of pregnancy.

Lactation

Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole and its metabolites in milk. Breastfeeding should be discontinued during treatment with CANESTEN® 1 VC.

DOSAGE AND DIRECTIONS FOR USE:

CANESTEN® 1 VC is a single dose treatment. The content of the applicator of CANESTEN® 1 VC (about 5 g) should be inserted as deeply as possible into the vagina in the evening before going to bed. Insertion is best achieved when lying back with the legs slightly drawn up.

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SIDE EFFECTS:

The following adverse reactions have been identified during post-approval use of CANESTEN® 1 VC. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to estimate their frequency.

Immune system disorders

Allergic reaction (syncope, hypotension, dyspnoea, urticaria)

Gastrointestinal disorders

Abdominal pain

Reproductive system and breast disorders

Genital peeling, pruritus, rash, oedema, erythema, discomfort, burning, irritation, pelvic pain, vaginal haemorrhage.

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF ITS TREATMENT:

See side-effects. Gastro-intestinal disturbances and central nervous system depression may follow accidental ingestion. Treatment is symptomatic and supportive.

IDENTIFICATION: Soft, white cream.

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

STORAGE INSTRUCTIONS: Store at or below 25 ºC. Keep out of the reach of children.

REGISTRATION NUMBER: U/20.2.2/205

PROFESSIONAL INFORMATION

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

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

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

Thereafter the date of the most recently revised professional information as approved by Council: 12 December 2017

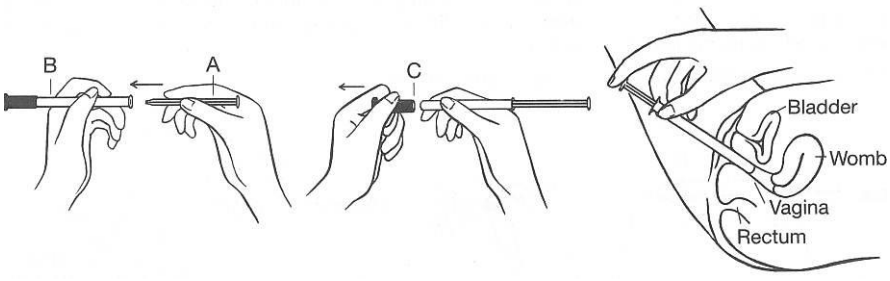
Inserting the applicator:

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.



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