SCHEDULING STATUS: S1

PROPRIETARY NAME AND DOSAGE FORM:

CANESTEN®
Vaginal Cream 1 %

COMPOSITION:

Each gram contains (as an active ingredient): Clotrimazole 10 mg.

Inactive ingredients: Benzyl alcohol 2 % (as preservative), cetostearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, sorbitan monostearate, purified water.

CATEGORY AND CLASS:

A 20.2.2 Fungicides

PHARMACOLOGICAL ACTION:

Pharmacodynamic Properties

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

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

CONTRAINDICATIONS:

- Hypersensitivity to clotrimazole or any of the excipients of CANESTEN® 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. Patient 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 preparations should not be used while using CANESTEN® Vaginal Cream.
- Avoidance of vaginal intercourse is recommended in case of vaginal infection and while using CANESTEN® Vaginal Cream.
- CANESTEN® Vaginal Cream is intended for use by adults and children 12 years of age and older only.

CANESTEN® Vaginal Cream 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® Vaginal Cream.

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 candidiasis infection have resolved.

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

Special Precautions:

Contact with eyes should be avoided.

Effects on ability to drive and use machines:

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

INTERACTIONS:

Concomitant medication with CANESTEN® Vaginal Cream and oral tacrolimus (FK-506; immunosuppressant) may 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 and efficacy of CANESTEN® Vaginal Cream in pregnancy has not been established.

Pregnancy:

There is limited amount of data from the use of CANESTEN® Vaginal Cream 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® Vaginal Cream during the first trimester of pregnancy.

During pregnancy the treatment should be carried out with CANESTEN® vaginal tablets, without using an applicator.

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® Vaginal Cream.

DOSAGE AND DIRECTIONS FOR USE:

CANESTEN® Vaginal Cream 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.

The content of 1 applicator of CANESTEN® Vaginal Cream (about 5 g) should be inserted each evening on 6 successive days.

SIDE EFFECTS:

The following adverse reactions have been identified during post-approval use of CANESTEN® Vaginal Cream. 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 - (this is a result of the natural exfoliation process of removing damaged vaginal epithelium), pruritus, rash, oedema, erythema, discomfort, burning, irritation, pelvic pain, vaginal haemorrhage.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:

See side effects. In case of accidental ingestion, gastro-intestinal disturbances and central nervous system depression may occur. Treatment is symptomatic and supportive.

IDENTIFICATION:

A soft, white cream.

PRESENTATION:

Collapsible aluminium tube of 35 g with 6 vaginal applicators packed into a carton.

Collapsible aluminium tube of 50 g with 6 vaginal applicators packed into a carton.

STORAGE INSTRUCTIONS:

Store at or below 25 °C. Keep out of the reach of children.

REGISTRATION NUMBER:

K/20.2.2/187

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Bayer (Pty) Ltd

27 Wrench Road, Isando, 1600, South Africa

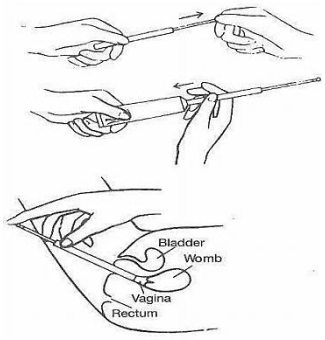
Co. Reg. No. 1968/011192/07

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

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

The date of the most recently revised professional information 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	PIM 81/14.17/1395
NAMIBIA	NS1 90/20.2.2/00356
BOTSWANA	S2 BOT0801235

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