Professional Information Human Medicine

The under-mentioned information with regard to this medicine shall appear on the package insert. The information shall be presented in the format stipulated, provided that the Council may authorise any deviation from such information or such format (refer to Regulation 9 of the Act).

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SCHEDULING STATUS:

S1

PROPRIETARY NAME AND DOSAGE FORM:

CANESTEN® DUOPAK

Vaginal Tablet and Cream

COMPOSITION:

Vaginal Tablet contains:

Active ingredient: Clotrimazole 500 mg

Inactive ingredients: Calcium lactate pentahydrate, cellulose microcrystalline, crospovidone, hypromellose 15 cP, lactic acid, lactose monohydrate, magnesium stearate, maize starch, silica colloidal anhydrous.

10 g Cream contains:

Active ingredient: Clotrimazole 100 mg

Inactive ingredients: Benzyl alcohol 2 % m/m (as preservative), cetostearyl alcohol, cetyl palmitate, octyldodecanol, polysorbate 60, sorbitan stearate, 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 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:

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

Cream: Candida infections of the labia and adjacent areas as well as candidal balanitis.

CONTRAINDICATIONS:

Hypersensitivity to clotrimazole or any of the ingredients of CANESTEN® DUOPAK.

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. The 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 this CANESTEN® DUOPAK.
- Avoidance of vaginal intercourse is recommended in case of vaginal infection and while using this CANESTEN® DUOPAK.
- During pregnancy the vaginal tablet should be inserted without an applicator.
- **CANESTEN® DUOPAK may reduce the effectiveness and safety of latex products such as condoms and diaphragms. Additional contraceptive measures are required when using CANESTEN® DUOPAK.**

  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.

- CANESTEN® DUOPAK is intended for use by adults and children 12 years of age and older only.
- Cetostearyl alcohol contained in the CANESTEN® DUOPAK Cream may cause local skin reactions (e.g. contact dermatitis).

Effects on ability to drive and use machinery:

CANESTEN® DUOPAK has no or negligible influence on the ability to drive and use machinery.

INTERACTIONS:

Concomitant medication with CANESTEN® DUOPAK and oral tacrolimus (FK-506; immunosuppressant) leads 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® DUOPAK have not been established in pregnancy.

Pregnancy:

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

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

Lactation:

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

DOSAGE AND DIRECTIONS FOR USE:

CANESTEN® Vaginal Tablet should be inserted as deeply as possible into the 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.

CANESTEN® Vaginal Tablet needs moisture in the vagina to dissolve completely, otherwise non-dissolved pieces of the vaginal tablet might crumble out of the vagina. To prevent this, it is important to insert the medication as deeply as possible into the vagina at bedtime. Should the vaginal tablet not dissolve completely within one night, the use of CANESTEN® vaginal cream should be considered.

CANESTEN® Cream is applied thinly to the affected areas (from the external genital organs to the anus in woman; glans and prepuce in men) 2 - 3 times a day and rubbed in. The usual period of treatment is 1 - 2 weeks.

SIDE EFFECTS:

The following adverse reactions have been identified during post-approval use of CANESTEN® DUOPAK. 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 OVER-DOSAGE AND PARTICULARS OF ITS TREATMENT:

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

IDENTIFICATION:

Vaginal Tablet: Nearly white to slightly yellowish oblong vaginal tablet with the word BAYER on one side and MU on the other side.

Cream: A soft white cream.

PRESENTATION:

One Vaginal Tablet of 500 mg sealed in aluminium foil, an applicator and a 10 g collapsible aluminium tube of Cream placed into an outer carton.

STORAGE INSTRUCTIONS:

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

REGISTRATION NUMBER:

30/20.2.2/0111

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

Bayer (Pty) Ltd

27 Wrench Road, Isando, 1600

South Africa

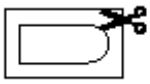
Co. Reg. No. 1968/011192/07

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

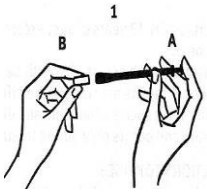
The date on the registration certificate of the medicine: 30 August 1996

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

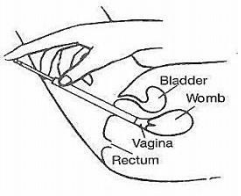
Prior to application remove one tablet from the aluminium foil (as illustrated).



Directions for using the Applicator :



1. Pull out plunger A until it stops. Place a vaginal tablet into the applicator B.
2. Insert applicator containing the tablet carefully and as deeply as possible into vagina (preferably lying on your back).
3. Push plunger A until it stops, thereby depositing the tablet into the vagina.
4. Remove the applicator.



Important Notice :

The product may only be used during pregnancy when prescribed by a doctor. Pregnant women should follow the instructions of their doctor strictly. During pregnancy, the tablet should be inserted without the applicator.

Botswana	S3 BOT0500736
Namibia	NS1 04/20.2.2/0634