Canesten DUOPAK

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

CANESTEN® DUOPAK

Vaginal Tablet 500 mg and Cream 100 mg

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

CANESTEN® DUOPAK is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use CANESTEN® DUOPAK carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CANESTEN® DUOPAK 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® DUOPAK CONTAINS:

Vaginal Tablet

The active ingredient is: Clotrimazole 500 mg.

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

Cream

The active ingredient is: Clotrimazole 10 mg/g

The other ingredients are: Benzyl alcohol 2 %, cetostearyl alcohol, cetyl palmitate, octyldodecanol, polysorbate 60, sorbitan stearate, purified water.

WHAT CANESTEN® DUOPAK IS USED FOR:

Vaginal Tablet is used for the relief of vaginal itching, burning and discharge associated with vaginal yeast infections.

Cream is used for candida infections of the labia and adjacent areas as well as inflammation of the glans and prepuce of the sexual partner.

BEFORE YOU USE CANESTEN® DUOPAK:

Do not use CANESTEN® DUOPAK:

- If you are hypersensitive (allergic) to clotrimazole or any of the other ingredients of CANESTEN® DUOPAK.
- If you are under 12 years of age.
- If you are having your menstrual period.

Take special care with CANESTEN® DUOPAK:

- 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 while using CANESTEN® DUOPAK 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.
- **CANESTEN® DUOPAK may reduce the effectiveness and safety of latex products such as condoms and diaphragms**. **You will need to take additional contraceptive measures while using CANESTEN® DUOPAK.**
- 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.
- CANESTEN® Cream contains cetostearyl alcohol which may cause local skin reactions (e.g. rash).
- During pregnancy the CANESTEN® Vaginal Tablet should be inserted without using an applicator.

- Recurrent infections may indicate an underlying medical cause. You should seek medical advice if symptoms return within 2 months.
- You should not use tampons, intravaginal douches, spermicides or other vaginal preparations while using CANESTEN® DUOPAK.

Pregnancy and Breastfeeding:

- If you are pregnant or breastfeeding your baby while using this medicine, please consult your doctor, pharmacist or other health care professional for advice before using this medicine.
- Safety and efficacy of CANESTEN® DUOPAK has not been established in pregnancy.
- CANESTEN® DUOPAK should not be used in the first three (3) months of pregnancy.
- Breastfeeding should be discontinued during treatment with CANESTEN® DUOPAK.
- During pregnancy the treatment should be carried out with CANESTEN® Vaginal Tablet since it can be inserted without using an applicator.

Driving and using machinery:

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

Using other medicines with CANESTEN® DUOPAK:

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

Using CANESTEN® DUOPAK together with tacrolimus or sirolimus may lead to increased tacrolimus or sirolimus blood levels. If you are taking one of these drugs, you will have to be monitored for tacrolimus or sirolimus overdosage.

HOW TO USE CANESTEN® DUOPAK:

Always use CANESTEN® DUOPAK 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:

Vaginal Tablet:

- Use the applicator to insert CANESTEN® Vaginal Tablet 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 (see diagram below).
- During pregnancy, the CANESTEN® Vaginal Tablet should be inserted without the applicator.

CANESTEN® vaginal tablets need 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.

Cream:

- Apply CANESTEN® Cream 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 with Vaginal Cream is 1 - 2 weeks.

It is recommended that the treatment should be timed so as to avoid menstrual period.

If you use more CANESTEN® DUOPAK than you should:

In the event of overdosage, 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® DUOPAK:

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

POSSIBLE SIDE EFFECTS:

CANESTEN® DUOPAK can have side effects.

Not all side effects reported for CANESTEN® DUOPAK 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 health care professional for advice.

If any of the following happens, stop using CANESTEN® DUOPAK 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® DUOPAK)
- 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® DUOPAK. 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, 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® DUOPAK:

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Do not use CANESTEN® DUOPAK after the expiry date on the carton and tube.

Return all unused medicine to your pharmacist.

Do not throw away unused medicine in drains or sewerage systems (e.g. toilets)

PRESENTATION OF CANESTEN® DUOPAK:

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 a carton.

IDENTIFICATION OF CANESTEN® DUOPAK:

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.

REGISTRATION NUMBER:

30/20.2.2/0111

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

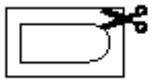
Tel No.: +27 (0) 11 921 5000

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

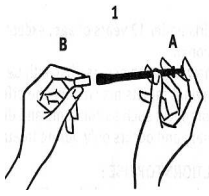
The date on the registration certificate of the medicine: 30 August 1996

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

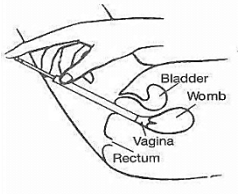
Prior to application remove one tablet from the aluminium foil (as illustrated).



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.

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Manufactured and packed by:

Cream: Kern Pharma S.L., Spain under licence by Bayer AG
Vaginal Tablet: Bayer AG, Germany.

The professional Information is available online at www.bayer.co.za