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.

Canesten DUOPAK

- 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:

Canesten DUOPAK

- 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 30 °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

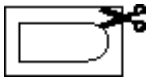
Tel No.: +27 (0) 11 921 5000

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

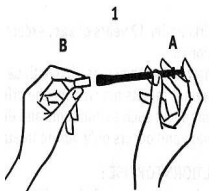
The date on the registration certificate of the medicine: 30 August 1996

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

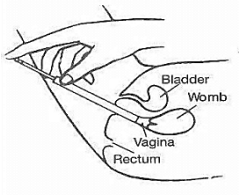
Prior to application remove one tablet from the aluminium foil (as illustrated).



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.

BOTSWANA	S3 BOT0500736
NAMIBIA	NS1 04/20.2.2/0634

Manufactured for Bayer (Pty) Ltd. by:
GP Grenzach Produktions GmbH Emil-Barell-Straße 7, 79639 Grenzach-Wyhlen, Germany

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

Canesten DUOPAK

PASIëNT SE INLIGTINGSBLAD

SKEDULERINGSTATUS S1

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM

CANESTEN® DUOPAK
Vaginale Tablet 500 mg en Room 100 mg

Lees alles op hierdie blaadjie noukeurig, want dit bevat belangrike inligting vir u.

CANESTEN® DUOPAK is sonder ‘n geneesheer se voorskrif beskikbaar vir u om ‘n ligte siekte te behandel. Ewewel, moet u CANESTEN® DUOPAK steeds versigtig gebruik om die beste resultate daarvan te kry.

- Hou hierdie blaadjie. U sal dit dalk weer wil lees.
- Moenie CANESTEN® DUOPAK met enige ander persoon deel nie.
- Vra u apteker indien u meer inligting of raad nodig het
- U moet u geneesheer raadpleeg, indien u simptome agteruitgaan of nie na 7 dae verbeter het nie.

WAT CANESTEN® DUOPAK BEVAT:

Vaginale Tablet:

Die aktiewe bestanddeel is: Klotrimasool 500 mg.

Die ander bestanddele is: Kalsiumlaktaatpentahidraat, mikrokristallynsellulose, krospovidoon, hipromellose 15 cP, laktiensuur, laktosemonohidraat, magnesiumstearaat, mieliestysel, anhidriese kolloïedale silika.

Room:

Die aktiewe bestanddeel is: Klotrimasool 10 mg/g.

Die ander bestanddele is: Bensielalkohol 2 % (as preserveermiddel), setostearielalkohol, setielpalmitaat, oktieldodekanol, polisorbaat 60, sorbitaanmonostearaat, gesuiwerde water.

WAARVOOR WORD CANESTEN® DUOPAK GEBRUIK:

Vaginale Tablet word vir die verligting van vaginale jeuk, brand en afskeiding wat met vaginale gisinfeksies vereenselwig word, gebruik.

Room word vir kandida-infeksies van die skaamlippe en nabyliggende areas, asook vir inflammasie van die glans en voorhuid van die seksuele gesel gebruik.

VOORDAT U CANESTEN® DUOPAK GEBRUIK:

Moenie CANESTEN® DUOPAK gebruik nie:

- Indien u vir klotrimasool of vir enige van die bestanddele in CANESTEN® DUOPAK hipersensitief (allergies) is nie
- Indien u jonger as 12 jaar is
- Indien u menstrueer.

Neem spesiale sorg met CANESTEN® DUOPAK:

- Indien u ‘n koors, lae abdominale pyn, rugpyn, vaginale afskeiding wat sleg ruik, naarheid, vaginale bloeding, en/of gepaardgaande pyn in u skouer het, moet u u geneesheer raadpleeg.
- Vermy vaginale geslagsomgang, terwyl u CANESTEN® DUOPAK gebruik, aangesien dit vaginale infeksie kan veroorsaak en u gesel kan ook besmet word.
- Indien simptome vir meer as 7 dae voortduur, kan u ‘n toestand hê wat mediese behandeling benodig. U moet u geneesheer raadpleeg.
- **CANESTEN® DUOPAK kan die doeltreffendheid en veiligheid van lateksprodukte soos kondome en diafragmas verminder. Dit sal nodig wees dat u bykomende voorbehoedmaatreëls moet neem, terwyl u CANESTEN® DUOPAK gebruik.**
- Aangesien CANESTEN die doeltreffendheid en veiligheid van kondome en diafragmas kan verminder, is dit beter dat u vaginale geslagsomgang tydens behandeling vermy, om oordrag van MIV en seksueel oordraagbare siektes te voorkom, totdat simptome van die kandidiase infeksie opgeklaar het.
- CANESTEN® Room bevat setostearielalkohol wat plaaslike velreaksies (bv. uitslag) veroorsaak.
- Gedurende swangerskap moet CANESTEN® Vaginale Tablet sonder die gebruik van ‘n toediener ingeplaas word.
- Herhalende infeksies kan op ‘n onderliggende mediese oorsaak dui. U moet mediese advies inwin, indien simptome binne 2 maande terugkeer.
- U moet nie tamponne, intravaginale uitspoelings, spermisiede of ander vaginale produkte tydens gebruik van CANESTEN® DUOPAK gebruik nie.

Swangerskap en Borsvoeding

- Indien u swanger is of u baba borsvoed, raadpleeg asseblief u geneesheer, apteker of ander gesondheidsorgdeskundige voordat u hierdie medisyne neem.
- Veiligheid en doeltreffendheid van CANESTEN® DUOPAK is nie in swangerskap vasgestel nie.
- U moet nie CANESTEN® DUOPAK gedurende die eerste drie (3) maande van swangerskap gebruik nie.
- Borsvoeding moet tydens behandeling met CANESTEN® DUOPAK gestaak word.
- Gedurende swangerskap moet behandeling met CANESTEN® Vaginale Tablet plaasvind, aangesien dit sonder die gebruik van 'n toediener ingeplaas kan word.

Bestuur en gebruik van masjiene

CANESTEN® DUOPAK het geen of onbeduidende invloed op die vermoë om te bestuur of gebruik van masjiene nie.

Gebruik van ander medisyne met CANESTEN® DUOPAK:

Vertel altyd u gesondheidsorgdeskundige, indien u enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in).

Die gebruik van CANESTEN® DUOPAK saam met takrolimus of sirolimus kan tot verhoogde takrolimus- of sirolimusbloedvlakke lei. Indien u een van hierdie geneesmiddels neem, moet u deeglik vir simptome van takrolimus- of sirolimusoordosering gemoniteer word.

HOE OM CANESTEN® DUOPAK TE GEBRUIK:

Gebruik CANESTEN® DUOPAK altyd presies soos u geneesheer of apteker aanbeveel het. U moet u geneesheer of apteker vra, indien u onseker is.

Die gewone dosis is:

Vaginale Tablet:

- Gebruik die toediener om die CANESTEN® Vaginale Tablet so diep as moontlik in die vagina in die aand voor slapenstyd in te plaas.
- Inplasing is die beste wanneer u op u rug lê met die bene effens opgetrek (sien diagram onder).
- Die CANESTEN® Vaginale Tablet moet sonder die toediener gedurende swangerskap ingeplaas word.

CANESTEN® Vaginale Tablette benodig vogtigheid in die vagina om heeltemal op te los, andersins kan onopgeloste stukkies van die vaginale tablet as krummels uit die vagina uitkom. Om dit te voorkom, is dit belangrik om die medikasie so diep as moontlik in die vagina voor slapenstyd in te plaas.

Room:

- CANESTEN® Room moet dun aan die aangetaste areas (van die eksterne genitale organe na die anus van die vrou aangewend word; glans en voorhuid in mans) 2 - 3 maal per dag en ingevryf word. Die gewone behandelingstydperk is 1 – 2 weke.
- Die gewone tydperk van behandeling met die Vaginale Room is 1 - 2 weke.

Daar word aanbeveel dat die behandeling so beplan word dat dit die maandstonde vermy.

Indien u meer CANESTEN® DUOPAK gebruik het as wat u moes:

In die geval van ‘n oordosis, raadpleeg u geneesheer of apteker. Indien hulle nie beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

In die geval van onopsetlike mondelikse inname, kan maagpyn, verlies van bewussyn en kortasemheid voorkom. Behandeling is simptomaties en ondersteunend.

Indien u vergeet het om ‘n dosis van CANESTEN® DUOPAK te gebruik:

Moenie ‘n dubbele dosis gebruik om te vergoed vir die vergete indiwiduele dosisse nie.

MOONTLIKE NEWE-EFFEKTE:

CANESTEN® DUOPAK kan newe-effekte hê.

Nie al die newe-effekte wat vir CANESTEN® DUOPAK aangemeld was, is in hierdie blaadjie ingesluit nie. Indien u algemene gesondheid agteruitgaan of indien u enige ongewenste effekte ondervind, terwyl u hierdie medisyne gebruik, raadpleeg asseblief u geneesheer, apteker of ander gesondheidsorgdeskundige.

Indien enige van die volgende gebeur, staak gebruik van CANESTEN® DUOPAK en vertel u geneesheer onmiddellik of gaan na die ongevalle afdeling van u naaste hospitaal:

- Netelroos of veluitslag
- Tydelike verlies van bewussyn – (dit is as gevolg van ‘n allergiese reaksie vir die bestanddele van CANESTEN® DUOPAK.)
- Jeuk
- Vaginale edeem (swelling)

Hierdie is almal baie ernstige newe-effekte. Indien u hulle ondervind, kan u ‘n ernstige allergiese reaksie vir CANESTEN® DUOPAK hê. U kan dringend mediese aandag of hospitalisasie benodig.

Vertel u geneesheer onmiddellik of gaan na die ongevalle afdeling van u naaste hospitaal, indien u enige van die volgende oplet:

- Pelviese pyn
- Kortasemheid
- Vaginale bloeding

Hierdie is almal ernstige newe-effekte. U kan dringend mediese aandag benodig.

Vertel u geneesheer indien u enige van die volgende oplet:

- Abnormale lae bloeddruk – (simptome is duiseligheid/lighoofdigheid, floute, siekgevoel)
- Genitale afskilfering – (hierdie is as gevolg van die afskilferende proses van verwydering van die beskadigde vaginale epiteel)
- Rooiheid van die vel
- Ongerief
- Brandgevoel
- Irritasie
- Abdominale pyn.

Indien u enige newe-effekte oplet wat nie in hierdie blaadjie genoem is nie, lig asseblief u geneesheer of apteker in.

BERGING EN WEGDOEN VAN CANESTEN® DUOPAK:

Bewaar alle medisyne buite die bereik van kinders.

Bewaar by of benede 25 ºC.

Beskerm teen lig.

Moenie CANESTEN® DUOPAK na die vervaldatum wat op die karton gedruk is, gebruik nie.

Neem alle ongebruikte medisyne terug na u apteker.

Moenie ongebruikte medisyne in afvoerpype of rioolsisteme (bv. toilette) weggooi nie.

AANBIEDING VAN CANESTEN® DUOPAK:

Een Vaginale Tablet van 500 mg wat in aluminiumfoelie verseël is, ‘n toediener en ‘n 10 g voubare aluminium buis met

Room wat in ‘n buitekarton geplaas is.

IDENTIFIKASIE VAN CANESTEN® DUOPAK:

Vaginale Tablet: Amper wit to effense gelerige langwerpige vaginale tablet met die woord

BAYER aan die een kant en MU aan die ander kant.

Room: ‘n Sagte, wit room.

REGISTRASIENOMMER:

30/20.2.2/0111

NAAM, SAKEADRES EN TELEFOONNOMMER VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

Bayer (Edms) Bpk

Wrenchweg 27

Isando

1600

Maatskappy Reg. nr. 1968/011192/07

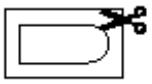
Tel: +27 (0) 11 921 5000

DATUM VAN PUBLIKASIE VAN DIE PASIëNT SE INLIGTINGSBLAD:

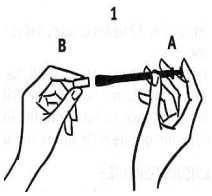
Die datum op die registrasiesertifikaat van die medisyne: 30 Augustus 1996

Die datum van die onlangste hersiende professionele inligting soos deur die Raad goedgekeur: 20 Maart 2018

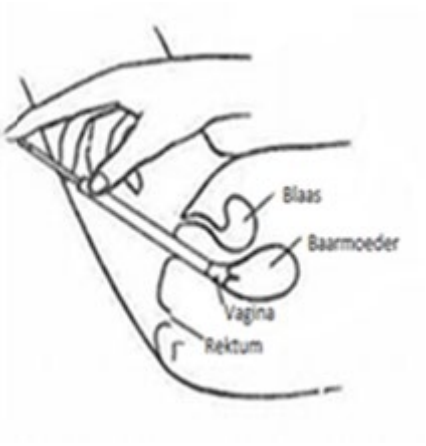
Verwyder een tablet van die aluminiumfoelie voor inplasing (sien illustrasie).



Aanwysings vir gebruik van die Toediener:



1. Trek die plons A totdat dit stop. Plaas ‘n vaginale tablet in die toediener B.
2. Druk toediener wat die tablet bevat so diep as moontlik in die vagina (verkieslik terwyl u op u rug lê).
3. Druk die plons A totdat dit stop, om die tablet in die vagina te plaas.



4. Verwyder die toediener.

Belangrike Nota:

Die produk moet slegs gedurende swangerskap gebruik word, indien dit deur ‘n geneesheer voorgeskryf is. Swanger vrouens moet die aanwysings van hul geneesheer streng navolg. Die tablet moet sonder die toediener gedurende swangerskap ingeplaas word.