

# Canesten®

## GYN

1 Day Therapy



For Single dose treatment  
 1 vaginal tablet of 0.5g with applicator  
 Broad-spectrum antimycotic with fungicidal action

### 1. WHAT IS CANESTEN GYN TREATMENT USED FOR?

Canesten Gyn treatment is used for fungal infection in the vaginal and vulva area. Canesten has a reliable action on dermatophytes, yeast and other fungi; it also acts on gram-positive microorganisms (Streptococci/Staphylococci/ Gardnerella vaginalis) and gram-negative microorganisms (Bacteroides).

### 2. WHAT IS VAGINAL YEAST INFECTION (THRUSH)?

Vaginal yeast infection is a common infection of the vagina area that is most commonly caused by an overgrowth of Candida albicans yeast. Although Candida albicans occurs naturally in the vagina, its overgrowth may lead to unpleasant symptoms.

#### Product Description

Biconvex White-pale Yellow pessary with 1 Rounded end.

#### Composition

1 vaginal tablet contains 0.5g clotrimazole

#### Therapeutic Indications

Infection of the genital region (vaginitis) caused by fungi (usually Candida) and super infections caused by clotrimazole-sensitive bacteria.

#### Dosage

For treatment of vaginal infections:

Single-dose treatment with Canesten GYN 1 Day Therapy:

1 vaginal tablet to be introduced in the evening before going to bed.

#### Contraindications

Hypersensitivity to clotrimazole or to any other component of the product.

#### Special Warnings and Special Precautions for Use

If you are experiencing a fever (temperature of 38°C or above), lower abdominal pain, back pain, foul smelling vaginal discharge, nausea, vaginal haemorrhage, and/or associated shoulder pain, you should consult a doctor.

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

Do not use tampons, intravaginal douches, spermicides or other vaginal products while using this product.

Avoidance of vaginal intercourse is recommended in case of vaginal infection and while using this product the partner could become infected. The sexual partner should also undergo local treatment if symptoms, e.g. pruritus, inflammation, etc. are present.

When used in pregnancy, the vaginal tablets should be inserted without using an applicator.

Keep medicine out of the sight and reach of children. Avoid contact with eyes. Do not swallow.

Clotrimazole 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). The effect is temporary and occurs only during treatment.

#### Interactions with Other Medicinal Products and Other Forms of Interaction

Concomitant medication with vaginal clotrimazole 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 overdose, if necessary by determination of the respective plasma levels.

#### Fertility, Pregnancy and Lactation

##### Fertility:

Animal studies have not demonstrated any effects of the drug on fertility.

##### Pregnancy:

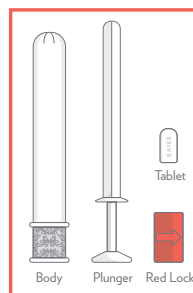
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Clotrimazole can be used during pregnancy, but only under the direction of a Health Care Professional. During pregnancy, the treatment should be carried out with clotrimazole vaginal tablets, since these can be inserted without using an applicator.

##### Lactation:

There are no data on the excretion of clotrimazole into human milk.

However, systemic absorption is minimal after administration and is unlikely to lead to systemic effects. Clotrimazole may be used during lactation.

### 3. HOW TO USE IT?

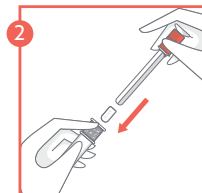


If product has been prescribed for you by your doctor, follow any instructions he/she may have given you.

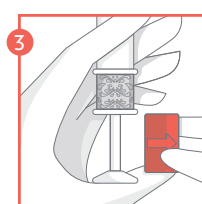
If you purchased this product without a prescription, follow these directions closely:

The applicator should be used to insert the vaginal tablet as deep as possible into the vagina, preferably before going to sleep.

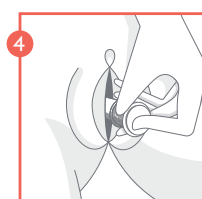
Wash your hands before removing the vaginal tablet and the applicator from the pack and again afterwards when you have used the applicator.



1. Remove the applicator from its packaging and pull out the plunger and red lock from the body.



2. Place the vaginal tablet into the open end of the body with the curved edge of the vaginal tablet facing down. Push the Plunger and Lock into the body until you feel a click.



3. Once you have felt the click, remove the Lock from the Plunger and then carefully insert the applicator into the vagina up to the patterned grip zone.



4. Hold the applicator body at the patterned grip zone and carefully push the plunger all the way until it stops to dispense the vaginal tablet. Insertion is best achieved when lying back with the legs slightly drawn up.

5. After use, disassemble all the components for cleaning and wash thoroughly in warm (not boiling) soapy water, rinse for 30 seconds and wipe the parts carefully. Store it in a clean and safe place.

For re-use, ensure the red lock is replaced on the plunger and repeat the process from Step 2.

After the final use, dispose of the applicator in a safe place, out of the reach of children.

The applicator cannot be flushed down the toilet.

Since the vaginal tablet need moisture in the vagina to dissolve completely, it may be helpful to wear a panty liner because it is quite common to notice a white chalky residue after using it. This does not mean that the treatment has not worked. However, if you notice pieces of undissolved vaginal tablet, speak to your doctor or a pharmacist, as the treatment may not have worked properly.

The symptoms of thrush should disappear within three days of treatment. If no improvement is seen after seven days or if symptoms return within 2 months you must tell your doctor.

A combination treatment is recommended (i.e vaginal cream and vaginal tablet) if the labia and adjacent areas are simultaneously infected.

The sexual partner should also undergo local treatment using an external cream if symptoms, e.g. pruritus, inflammation, etc. are present.

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

Do not use tampons, intravaginal douches, spermicides or other vaginal products while using this product.

Avoidance of vaginal intercourse is recommended in case of vaginal infection and while using this product because the partner could become infected and the effectiveness and safety of latex products such as condoms and diaphragms may be reduced.

During pregnancy, the vaginal tablets should be used and inserted without using an applicator. Intended for use by adults.

### Overdose

No risk of acute intoxication is seen as it is unlikely to occur following a single vaginal application of an overdose (application over a large area under conditions favorable to absorption) or inadvertent oral ingestion. There is no specific antidote.

### If you forget to use

When you remember, continue with your course of treatment. If you have forgotten for more than one day, your infection may not be fully treated, so if symptoms persist upon completion of this course, see your doctor.

### Effects on Ability to Drive and Use Machines

The medication has no or negligible influence on the ability to drive or use machinery.

## 4. UNDESIRABLE EFFECTS

Frequency not known. The following adverse reactions have been identified during post-approval use of Clotrimazole. As these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency.

- Immune system disorders: anaphylactic reaction, angioedema, hypersensitivity
- Vascular disorder: syncope, hypotension
- Respiratory, thoracic and mediastinal disorders: dyspnea
- Reproductive system and breast disorder disorders: vaginal exfoliation, vaginal discharge, vulvovaginal pruritus, vulvovaginal erythema, vulvovaginal discomfort, vulvovaginal burning sensation, vulvovaginal pain, vaginal haemorrhage
- Gastrointestinal disorders: abdominal pain, nausea
- Skin and Subcutaneous Tissue Disorders: rash, urticaria
- General disorders and administration site conditions: application site irritation, oedema, pain

## 5. STORAGE CONDITION

Keep this medicine out of the sight and reach of children. Store at or below 30°C.

## 6. FURTHER INFORMATION

**Pharmacological Properties**

**Pharmacodynamics Properties**

**Pharmacotherapeutic group:** Gynecological antiinfectives and antiseptics – imidazole derivatives

**ATC Code:** G01A F02

### Mechanism of action

Azoles (e.g. clotrimazole) are usually recommended for the local treatment of vulvovaginal candidosis that is characterized by vulvovaginal symptoms such as itching, burning, discharge, redness, swelling and soreness.

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

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

Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. The mode of action of clotrimazole is primarily fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. In-vitro activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci/Staphylococci/Gardnerella vaginalis), and gram-negative microorganisms (Bacteroides).

In vitro clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci – with the exception of Enterococci – in concentrations of 0.5-10 µg/ml substrate.

Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

### Pharmacokinetic Properties

Pharmacokinetic investigations after vaginal application have shown that only a small amount of clotrimazole (3-10%) is absorbed. Due to the rapid hepatic metabolism of absorbed clotrimazole into pharmacologically inactive metabolites the resulting peak plasma concentrations of clotrimazole after vaginal application of a 500mg dose were less than 10 ng/ml, suggesting that clotrimazole applied intravaginally is unlikely to lead to measurable systemic effects or side effects.

### Preclinical Safety Data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction and development.

### Incompatibilities

None known

### Presentation

Pack of 1 vaginal tablet with applicator.

### Imported & Marketed in Singapore by

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