

Clotrimazole

Canesten®



100 mg Vaginal Tablet

1. Name of the Product

Clotrimazole (Canesten®) 100 mg Vaginal Tablet

2. Description of the Product

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

3. What is in the Medicine?

100 mg Vaginal Tablet:

Each vaginal tablet contains:

Clotrimazole.....100 mg

4. Strength of the Medicine

100 mg Vaginal Tablet: Clotrimazole 100 mg

5. What is this Medicine used for?

Infections of the genital region (vaginitis) caused by fungi (usually *Candida*), and superinfections caused by clotrimazole-sensitive bacteria.

6. How much and how often should you use this Medicine?

The vaginal tablet 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.

Clotrimazole vaginal tablets need moisture in the vagina to dissolve completely, otherwise undissolved 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 a vaginal cream should be considered.

For treatment of vaginal infections:

6-day treatment with Clotrimazole (Canesten®) 100mg:

1 vaginal tablet to be introduced each evening on 6 successive days.

Generally:

If symptoms persist, the patient should consult a doctor.

The treatment can be repeated if necessary, however, recurrent infections may indicate an underlying medical cause.

Patient should seek medical advice if symptoms return within 2 months.

If the labia and adjacent areas are simultaneously infected, local treatment with an external cream should also be given in addition to the intravaginal treatment (combination treatment).

Intended for use by adults and children 12 years of age and older.

7. When should you not take this Medicine?

Hypersensitivity to the active substance or excipients (Calcium Lactate pentahydrate, Cellulose microcrystalline, Crospovidone, Hypromellose 15cP, Lactic Acid, Lactose monohydrate, Magnesium stearate, Maize starch, Silica colloidal anhydrous)

8. Care that should be taken when taking this Medicine?

If the patient has 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 the patient should consult a doctor.

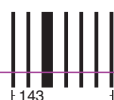
Treatment during the menstrual period should not be performed. The treatment should be finished before the onset of menstruation.

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.

Avoid contact with eyes. Do not swallow.





9. Undesirable Effects of this Medicine

Immune system disorders: anaphylactic reaction, angioedema, hypersensitivity

Vascular disorder: syncope, hypotension

Respiratory, thoracic and mediastinal disorders: dyspnea

Reproductive system and breast disorders: vaginal exfoliation, vaginal discharge, vaginal haemorrhage, vulvovaginal discomfort, vulvovaginal erythema, vulvovaginal burning sensation, vulvovaginal pruritus, vulvovaginal pain

Gastrointestinal disorders: abdominal pain, nausea

General disorders and administration site conditions: application site irritation, edema, pain

10. What other medicine or food should be avoided while taking this Medicine?

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 overdosage, if necessary by determination of the respective plasma levels.

11. What should you do if you miss a dose?

No available information.

12. Signs and Symptoms of Overdose

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

13. What to do when you have taken more than the recommended dosage?

There is no specific antidote.

14. How should you keep this Medicine?

Store at temperatures not exceeding 30°C.

Keep medicine out of the reach of children.

15. When should you consult your doctor?

If symptoms persist for more than 7 days, the patient may have a medical condition that requires treatment by a doctor.

Patient should seek medical advice if symptoms return within 2 months.

If the patient has 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 the patient should consult a doctor.

Manufacturer:

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Marketing Authorization Holder:

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If you want to report a product complaint or side effect, please contact your health care professional or the Philippine FDA at adr@fda.gov.ph

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