

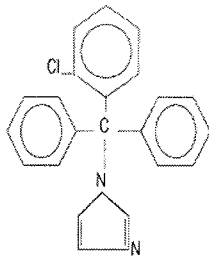
PRODUCT INFORMATION

CANESTEN® CLOTRIMAZOLE THRUSH TREATMENT ONCE PESSARY + CREAM

NAME OF DRUG

Clotrimazole

1-(o-chloro- α,α -diphenylbenzyl) imidazole



C₂₂H₁₇ClN₂

MW 344.84

DESCRIPTION

Clotrimazole is a colourless, crystalline, weakly alkaline substance, melting point 141° - 145°C, soluble in acetone, chloroform and ethanol and practically insoluble in water. It forms stable salts with both organic and inorganic acids. It is not photosensitive but is slightly hygroscopic and may be hydrolysed in acid media.

CANESTEN® CLOTRIMAZOLE THRUSH TREATMENT ONCE PESSARY + CREAM contains:

- Canesten® pessary containing 500mg of clotrimazole, together with lactose, cellulose-microcrystalline, lactic acid, crospovidone, calcium lactate, magnesium stearate, silicon dioxide, hypromellose, and starch-maize per pessary.
- Canesten® anti-fungal cream containing 10mg/gram (1%) of clotrimazole in a vanishing cream base of sorbitan monostearate, polysorbate 60, cetyl esters wax, cetostearyl alcohol, octyldodecanol, benzyl alcohol and water-purified.

PHARMACOLOGY

Clotrimazole, the active ingredient of Canesten, is an imidazole derivative with a broad spectrum antimycotic activity. The primary mode of action of Canesten appears to be on the cell membrane of the fungi, damaging the permeability barrier.

Studies using ¹⁴C-labelled clotrimazole have shown absorption of about 3% of the administered dose from normal or inflamed human vaginal mucosa (peak serum level of 0.03 ug/mL) 24 hours after insertion of a 100 mg tablet.

Studies in normal volunteers after vaginal insertion of one 500mg pessary showed that plasma levels of clotrimazole up to 10 ng/mL were reached during the period assay (up to 72 hours after insertion). Significant concentrations of clotrimazole were present in the vaginal secretion for up to 48 hours after insertion.

Pharmacokinetic investigations after dermal application have shown that only a small amount of clotrimazole (< 2 % of the dose) is absorbed. The resulting peak plasma concentrations of the active ingredient are < 10ng/ml (ie. below the detection limit) and do not lead to measurable systemic effects or side effects.

INDICATIONS

Canesten® Clotrimazole Thrush Treatment Once Pessary + Cream is indicated for the treatment of candidal infections of the vagina and vulvovagina and sexual partner.

CONTRAINDICATIONS

Known hypersensitivity to clotrimazole and/or to any of the excipients.

PRECAUTIONS

If evidence of local intolerance develops, consider withdrawal of the drug and institution of appropriate therapy.

Canesten pessary is for intravaginal use only and is not to be taken orally.

Canesten antifungal cream is not intended for ophthalmic use.

Canesten Vaginal Cream /pessaries may reduce the effectiveness and safety of latex products, such as condoms and diaphragms. This effect is temporary and occurs only during treatment.

Carcinogenicity/mutagenicity

No carcinogenicity or mutagenicity has been observed in animal studies.

Use in Pregnancy (Category A)

In the first trimester of pregnancy, intravaginal Canesten should be used only when the medical practitioner considers it essential for the welfare of the patient. Administration of Canesten pessaries to a small number of women in the 2nd and 3rd trimesters of pregnancy has produced no obvious untoward effect on the course of the pregnancy or on the foetus. This limited experience is insufficient to detect with reasonable certainty events occurring with an incidence of less than 3%.

Use in Lactation

Although systemic absorption following topical and vaginal administration is low, caution should be exercised when clotrimazole is administered to nursing mothers as there is no information on whether or not clotrimazole is excreted in breast milk.

Interactions with other Drugs

Not reported with topical forms of Canesten.

Effects on Laboratory Tests

Not known.

ADVERSE REACTIONS

Canesten anti-fungal cream is well tolerated after local application. The following have been reported infrequently: erythema, stinging, blistering, peeling, oedema, pruritus, and general irritation.

Eleven (1.6%) of 689 patients treated with Canesten pessaries complained of possibly drug-related effects. Mild burning occurred in four patients while other complaints such as skin rash and lower abdominal cramps were mentioned. Slight urinary frequency and burning or irritation in the sexual partner occurred rarely. In no case was it necessary to discontinue Canesten pessaries.

DOSAGE AND ADMINISTRATION

Canesten pessary should be inserted gently and as deeply as possible into the vagina, preferably at night. This is best achieved using the plastic applicator provided and following the directions on the patient instruction sheet. In late pregnancy digital insertion may be preferable to the use of the applicator. The 500 mg Canesten pessary provides therapy for three to four days as it creates high intravaginal concentrations of clotrimazole, however the symptoms may persist for these three to four days.

Canesten anti-fungal cream may be used in conjunction with Canesten pessary in the management of candidal vulvovaginitis or infection of the peri-anal area while application of the cream to the glans penis of the partner may help prevent reinfection of the female. This should be applied thinly to the affected areas (external genital organs to the anus in the woman; glans and prepuce in men) 2 - 3 times daily and rubbed in.

It is suggested that the treatment be timed so as to avoid the menstrual period and to be complete before the onset of menstruation. If the treatment does coincide with a menstrual period, use sanitary pads not tampons during therapy.

A doctor should be consulted before use in the following instances:

If it is the first occurrence of the problem,

If there have been more than two infections in the previous six months,

If pregnant or diabetic,

If under 18 years of age,
If not better in four days.

OVERDOSAGE

Not applicable.

PRESENTATION

Canesten® Clotrimazole Thrush Treatment Once Pessary + Cream contains one Canesten pessary containing 500 mg of clotrimazole sealed in aluminium foil with a plastic applicator. Plus, one tube containing 10 grams of Canesten anti-fungal cream, 10 mg clotrimazole per gram (1%)

NAME AND ADDRESS OF SPONSOR

Bayer Australia Limited
ACN 000 138 174
Consumer Care Business Group
875 Pacific Highway
Pymble NSW 2073

TEXT APPROVED by TGA:

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