

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Canesten Thrush Combi Internal & External Creams 10% w/w / 2% w/w vaginal cream & cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Canesten Thrush Internal Cream contains Clotrimazole 10% w/w.

Canesten Thrush External Cream contains Clotrimazole 2% w/w.

Excipients with known effect:

Canesten Thrush Internal Cream contains:

Cetostearyl alcohol 35mg in each gram of cream

Benzyl alcohol 10mg in each gram of cream

Canesten Thrush External Cream contains:

Cetostearyl alcohol 100mg in each gram of cream

Benzyl alcohol 20mg in each gram of cream

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Vaginal cream

White vaginal cream

Cream

White cream

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

The internal cream is recommended for the treatment of candidal vaginitis.

The external cream is recommended for the treatment of candidal vulvitis. It should be used as an adjunct to treatment of candidal vaginitis.

These products should only be used if candidal vulvovaginitis (thrush) was previously diagnosed by a doctor.

4.2 Posology and method of administration

Adults

The internal cream should be administered intravaginally using the applicator supplied. The contents of the filled applicator (5g) should be inserted as deeply as possible into the vagina, preferably at night.

The external cream should be thinly applied to the vulva and surrounding area, two or three times daily and rubbed in gently.

Treatment with the external cream should be continued until symptoms of the infection disappear. However, if after concomitant treatment of the vaginitis, the symptoms do not improve within seven days, the patient should consult a physician.

Children

Not for use in children under 16.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Do not use to treat nail or scalp infections.

4.4 Special warnings and precautions for use

These products contain cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis). They also contain benzyl alcohol which may cause allergic reactions and mild local irritation.

Before using Canesten Thrush Combi Internal & External Creams medical advice must be sought if any of the following are applicable: -

- more than two infections of candidal vaginitis in the last 6 months
- previous history of a sexually transmitted disease or exposure to partner with sexually transmitted disease
- pregnancy or suspected pregnancy
- aged under 16 or over 60 years
- known hypersensitivity to imidazoles or other vaginal antifungal

products

The creams should not be used if the patient has any of the following symptoms whereupon medical advice should be sought: -

- irregular vaginal bleeding
- abnormal vaginal bleeding or a blood-stained discharge
- vulval or vaginal ulcers, blisters or sores
- lower abdominal pain or dysuria
- any adverse events such as redness, irritation or swelling associated with the treatment
- fever or chills
- nausea or vomiting
- diarrhoea
- foul smelling vaginal discharge

Treatment during the menstrual period should be avoided due to the risk of the cream being washed out by the menstrual flow. 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.

Vaginal intercourse should be avoided in case of vaginal infection and while using this product because the partner could become infected.

If no improvement in symptoms is seen after 7 days the patient should consult their doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

Concomitant treatment with vaginal clotrimazole and oral tacrolimus (FK-506; immunosuppressant) might lead to increased tacrolimus plasma levels and similarly with sirolimus. Patients should thus be closely monitored for signs and symptoms of tacrolimus or sirolimus overdose, if necessary by determination of the respective plasma levels.

4.6 Fertility, pregnancy and lactation

Pregnancy:

There are limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at

high oral doses (see section 5.3). At the low systemic exposures of clotrimazole following vaginal treatment, harmful effects with respect to reproductive toxicity are not predicted.

Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

During pregnancy the treatment should be carried out with clotrimazole pessary, 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.

Fertility:

No human studies of the effects of clotrimazole on fertility have been performed, however, animal studies have not demonstrated any effects of the drug on fertility.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Frequency not known. As the listed undesirable effects are based on spontaneous reports, assigning accurate frequency of occurrence for each is not possible.

Immune system disorders: anaphylactic reaction, angioedema, hypersensitivity.

Canesten Internal Cream

Vascular disorder: syncope, hypotension

Respiratory, thoracic and mediastinal disorders: dyspnea

Gastrointestinal disorders: abdominal pain, nausea.

Skin and Subcutaneous Tissue Disorders: rash, urticaria, pruritus

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

General disorders and administration site conditions: application site irritation, oedema, pain.

Canesten Cream

Vascular disorder: syncope, hypotension

Respiratory, thoracic and mediastinal disorders: dyspnea

Skin and subcutaneous tissue disorders: blister, dermatitis contact, erythema, paraesthesia, skin exfoliation, pruritus, rash, urticaria, stinging skin/burning sensation skin.

General disorders and administration site conditions: application site irritation, application site reaction, oedema, pain.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 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 favourable to absorption) or inadvertent oral ingestion. There is no specific antidote.

However, in the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Gynaecological 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 fungal 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 – 8microgram/ml substrate. The mode of action of clotrimazole is 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.

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.

5.2. Pharmacokinetic Properties

Pharmacokinetic investigations after vaginal application have shown that only a small amount of clotrimazole (3 – 10% of the dose) 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, reflecting that clotrimazole applied intravaginally does not lead to measurable systemic effects or side effects.

5.3. Preclinical Safety Data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

Clotrimazole was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced fetal weights and decreased pup survival.

In rats clotrimazole and/or its metabolites were secreted into milk at levels higher than in plasma by a factor of 10 to 20 at 4 hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Canesten Thrush Internal Cream contains:

Sorbitan stearate
Polysorbate 60
Cetyl palmitate
Cetostearyl alcohol
Isopropyl myristate
Benzyl alcohol
Purified water

Canesten Thrush External Cream contains:

Sorbitan stearate
Polysorbate 60
Cetyl palmitate
Cetostearyl alcohol
Octyldodecanol
Benzyl alcohol
Purified Water

6.2. Incompatibilities

Not applicable

6.3 Shelf life

24 months.

6.4. Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Canesten Thrush Internal Cream:

A single dose applicator consisting of a body of HDPE, piston of LDPE, cap of LDPE, with a separate plunger of polystyrene. One applicator is contained in a blister pack. Pack size 5g.

Canesten Thrush External Cream:

The cream is filled into Aluminium tubes (10g) with internal lacquer coating, latex stopper and HDPE screw top.
The blister pack and tube are enclosed in a cardboard carton.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bayer plc
400 South Oak Way
Reading
RG2 6AD

8. MARKETING AUTHORISATION NUMBER

PL 00010/0301

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/08/2009

10 DATE OF REVISION OF THE TEXT

16/08/2021