

		Canesten Combo CMI 27 September 2007
	Consumer Medicine Information	

Canesten[®] Clotrimazole Thrush Treatment Once Pessary + Cream

Clotrimazole pessary 500 mg + cream 10 mg/g

What is in this leaflet

This leaflet answers some common questions about Canesten Thrush Treatment.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your pharmacist has weighed the risks of you using Canesten Thrush Treatment against the benefits they expect it will have for you.

If you have any concerns about using this treatment, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Canesten Thrush Treatment is used for

Canesten Thrush Treatment is used to treat a fungal infection in the vagina and vulval area (thrush).

This medicine belongs to a group of medicines called azole antifungals.

What is vaginal thrush?

Candida albicans is a yeast fungus that can multiply rapidly and cause symptoms in the vagina when other micro-organisms aren't present in a normal balance.

Some situations which can increase susceptibility to thrush are:

- diabetes
- obesity
- illness
- fatigue
- hormonal fluctuations (pregnancy, menstrual cycle, oral contraceptive pill, HRT)
- prolonged use of antibiotics or steroids

Thrush may cause the following symptoms:

- vaginal itching
- vaginal soreness

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- a white odourless discharge from the vagina (like cottage cheese)
- pain during intercourse

The symptoms below are **not** usually signs of thrush:

- abnormal or irregular vaginal bleeding
- blood stained discharge
- vulva or vaginal sores, ulcers or blisters
- lower abdominal pain
- pain when passing urine
- fever or chills
- foul smelling and/or unusual coloured discharge

See your doctor if you experience any of the above symptoms.

Ask your doctor or pharmacist if you have any questions about whether this medicine is suitable for you.

This medicine is available without a doctor's prescription, only through your pharmacist.

Before you use Canesten Thrush Treatment

When you must not use it

Do not use Canesten Thrush Treatment if you have an allergy to:

- any medicine containing *clotrimazole*
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include swelling to the area to which treatment has been applied; rash, itching or hives on the skin.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor or pharmacist.

Before you start to use it

See your doctor if:

- this is your first infection
- you are under 18 years of age
- you have had 3 or more infections in the last 6 months
- you have allergies to any other topical treatments

Tell your doctor if you are pregnant or think you might be.

You should see your doctor if you suspect you have thrush in the first three months of your pregnancy. Your doctor can discuss with you the risks and benefits involved with treatment.

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Tell your doctor if you are breast-feeding and want to use this treatment.

It is not known whether the active ingredient, clotrimazole, is excreted in breast milk. Your doctor will be able to discuss with you the risks and benefits involved with treatment.

Tell your doctor if you are diabetic.

Thrush in diabetics can mean that your blood sugar levels are not well controlled. Your doctor will be able to check this for you and advise treatment.

If you have not told your doctor about any of the above, do so before you start using Canesten Thrush Treatment.

Taking other medicines

There are no reports of Canesten Thrush Treatment interfering with other medicines.

How to use Canesten Thrush Treatment

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions below, or on the box, ask your doctor or pharmacist for help.

How to use it

Wash your hands thoroughly before handling the pessary or using the applicator.

To avoid the possibility of re-infection, strict personal hygiene must be observed.

Pessary

The pessary should preferably be inserted in the evening, just before bed time, with the use of the applicator. Using it before you go to sleep will have the best effect.

Loading the applicator

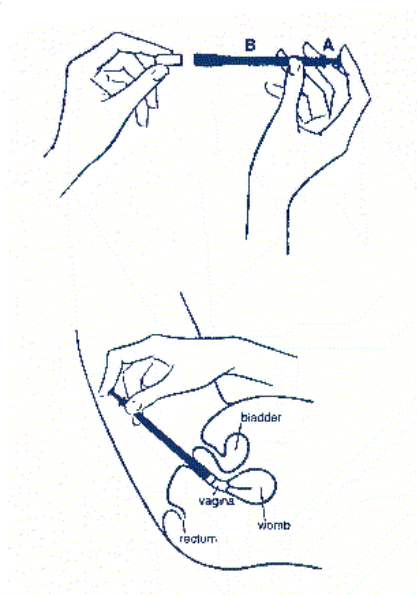
1. Wash your hands thoroughly.
2. Pull out the plunger until it stops (A).
3. Remove the pessary from the blister. Squeeze the cup end of the applicator (B) between your thumb and index finger to slightly flatten the cup.
4. Place the pessary into the flattened cup end of the applicator.

Inserting the applicator

5. Carefully insert the end of the applicator containing the pessary as gently and deeply into the vagina as possible. This is best achieved when lying on your back with your knees bent.
6. Hold the applicator in position and slowly push the plunger with the forefinger until it stops. This places the pessary in the vagina.
7. Remove the applicator from the vagina.

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8. Discard the applicator.



Anti-fungal cream

Use the cream on the external irritated area 2-3 times a day to relieve the symptoms of itching.

How long to use it

Insert one pessary, once.

Continue using the cream for as long as you experience itching or your doctor or pharmacist tells you to.

This treatment helps to relieve your condition. It is important to keep using it until the fungal infection is gone.

If you are not sure what to do, ask your doctor or pharmacist.

DO NOT TAKE THE PESSARY OR CREAM BY MOUTH.

Seek medical advice if you or anyone else has taken Canesten by mouth. Do this even if there are no signs of discomfort or poisoning.

You may need medical attention.

While you are using Canesten Thrush Treatment

Things you must do

Discontinue treatment and tell your doctor or pharmacist if you develop a local reaction to this product.

See your doctor if the symptoms are not gone within 4 days.

Things you must not do

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Do not use Canesten Thrush Treatment to treat any other complaints unless your doctor tells you to.

Do not give your treatment to anyone else, even if you suspect they have the same condition as you.

Things to be careful of

Canesten Thrush Treatment may reduce the effectiveness and safety of latex products such as condoms and diaphragms if it comes into contact with them.

Therefore you should prevent Canesten Thrush Treatment from coming into contact with these products. If Canesten Thrush Treatment does accidentally come into contact with a condom or diaphragm, replace the condom or diaphragm before using it as contraception.

Things that may help to resolve Thrush

Some self help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

- blot with toilet paper after urinating (instead of wiping back to front).
- change underwear, night attire, towels and linen daily.

Avoid where possible:

- perfumed toilet paper
- fragrant soaps and bath oils
- wearing tight or synthetic clothing
- douches or vaginal deodorants
- soaking in baths

Side effects

Tell your doctor or pharmacist if you experience discomfort while you are using Canesten Thrush Treatment.

This medicine helps most people with thrush but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- skin reaction to the pessary (burning, stinging, redness)
- skin reaction to the cream (stinging, redness, blistering, peeling, swelling, itching)

Any of the above may be signs of an allergic reaction. Your doctor or pharmacist may recommend you discontinue treatment if you experience these effects.

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After using Canesten Thrush Treatment

Storage

Keep the pessary in the protective blister pack until it is time to use it.

If you take the pessary out of the blister pack it may not keep well.

Keep the cream in the tube until it is time to use it.

If you take the cream out of the tube it may not keep well.

Keep your pessary and cream in a cool dry place where the temperature stays below 25°C.

Keep the treatment where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Expiry

Pessary

The expiry date is marked on the end panel of the carton and is also printed on the back of the blister. The date refers to the month and year of expiration e.g. 0805 refers to the eighth month of 2005. The product can be used until the end of this month.

Cream

The expiry date is marked on the end panel of the carton and is also printed on the crimp at the end of the tube. The date refers to the month and year of expiration e.g. 0805 refers to the eighth month of 2005. The product can be used until the end of this month.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Discard the medicine out of the reach of children.

Product description

What it looks like

The pessary is a white pellet-shaped pessary packaged in an aluminium blister.

The package carton contains a plastic applicator for insertion of the pessary. The plastic applicator is for use with Canesten pessary only. Discard the applicator after use.

The cream is a white opaque cream presented in a screw-cap tube containing 10 g of cream.

Ingredients

Canesten Thrush Treatment Once Pessary + Cream.

The pessary contains 500 mg clotrimazole as the active ingredient. It also contains:

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- lactose
- microcrystalline cellulose
- lactic acid
- maize starch
- crospovidone
- calcium lactate
- magnesium stearate
- silicon dioxide
- hypromellose

The cream contains 10 mg clotrimazole as the active ingredient in each gram of cream. It also contains:

- sorbitan monostearate
- Polysorbate 60
- cetyl palmitate
- cetostearyl alcohol
- octyldodecanol
- benzyl alcohol
- purified water

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

Canesten Thrush Treatment Once Pessary is made in Germany.

Canesten Thrush Treatment 10mg/g cream is made in Spain.

Canesten Thrush Treatment is distributed in New Zealand by:

Bayer New Zealand Limited
Consumer Care Business Group
3 Argus Place
Hillcrest
North Shore 0627
AUCKLAND
Toll Free: 0800 847 874

This leaflet was prepared on 27 September 2007.

Reference: Canesten Data Sheet dated 19 March 2007.

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