

PART III: CONSUMER INFORMATION

CANESORAL®

Fluconazole Capsule 150mg

This leaflet is part III of a three-part "Product Monograph" published when CanesOral® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CanesOral®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

CanesOral® is indicated for the treatment of vaginal yeast (fungal) infections. It can be taken anytime, anywhere to relieve itching, burning and discharge associated with vaginal yeast infections. CanesOral® is a clinically proven, effective single-dose cure for most vaginal yeast infections that starts to work in 1 day.

What is a Yeast Infection

A "yeast infection" may occur any time there is an overgrowth of yeast organisms in the vagina. The vagina normally has bacteria and yeast organisms present. Under some conditions, the number of yeast organisms rises, irritating the tissues of the vagina and vaginal opening.

Conditions that make this more likely to occur:

- illness
- use of antibiotics
- changes in hormone levels
- pregnancy
- use of oral contraceptive pills
- just before a woman's period
- diabetes
- hot humid weather
- continuous use of panty liners
- tight, non-breathing clothing
- nylon underwear, pantyhose, wet bathing suits or damp workout wear
- perfumed soaps, bubble baths or douching may cause vaginal irritation and upset the normal balance

Refrain from vaginal intercourse when you have a yeast infection to avoid infecting your partner and to minimize additional discomfort. If your partner has any genital

itching, redness or discomfort, they should talk to their doctor and mention that you are treating a yeast infection.

When a "yeast infection" occurs, the body responds with:

- an increase in vaginal secretions.
- secretions are generally thick and sticky (cheesy or curd-like, similar to cottage cheese), but odourless.
- secretions that are irritating to the tissues of the vaginal area
- itching, redness, and swelling of the vaginal area
- red spots or sores may develop, especially if the area has been scratched
- soreness in the vagina
- pain during sexual relations is common.

What it does:

CanesOral® is an antifungal medication. The active ingredient fluconazole works by stopping the growth of the fungi that cause vaginal yeast infections.

When it should not be used:

Do not use if you are:

- pregnant
- nursing
- allergic to fluconazole, related azoles (e.g. clotrimazole / miconazole) or other ingredients in the product
- taking allergy drugs (e.g. astemizole* / terfenadine*)
- taking cisapride*

*not marketed in Canada

What the medicinal ingredient is:

Fluconazole 150mg (Oral Capsule)

What the important nonmedicinal ingredients are:

Colloidal silicon dioxide, D&C Red #7, gelatin, lactose monohydrate, magnesium stearate, pregelatinized starch, propylene glycol, shellac, sodium laurel sulphate and titanium dioxide.

What dosage forms it comes in:

CANESORAL® is available in a single-dose foil blister. Each capsule contains 150 mg of fluconazole.

WARNINGS AND PRECAUTIONS

BEFORE USING CANESORAL® talk to your doctor or pharmacist if:

- you are having your first yeast infection
- you have frequent vaginal infections
- you are at increased risk for sexually transmitted diseases, have multiple sexual partners or change partners often
- you have heart disease
- using in children less than 12 years old

If you could become pregnant while taking CANESORAL®, you should consider using a reliable means of contraception, because the possible effects of this medication on a developing fetus are not known.

Yeast infections do not cause:

- Fever
- Chills
- Abdominal pain
- Nausea
- Vomiting
- Diarrhea
- Pain upon urination
- Unexplained pain in your lower back or either shoulder
- Foul-smelling discharge

Consult your doctor immediately if you have these symptoms, as they could be signs of a more serious condition.

INTERACTIONS WITH THIS MEDICATION

BEFORE you use CANESORAL® talk to your doctor or pharmacist if you are taking any other drug especially drugs for:

- AIDS/HIV (zidovudine)
- Allergies (astemizole*, terfenadine*)
- Asthma (theophylline)
- Antibiotics (rifabutin, rifampicin)
- Blood Thinners. (warfarin)
- Diabetes (glyburide, glipizide, tolbutamide)
- Diuretics (hydrochlorothiazide)
- Epilepsy (phenytoin)
- Immune System suppression (cyclosporine, tacrolimus)
- Stomach (cimetidine, cisapride*)
- Sedation (midazolam, triazolam)

* not marketed in Canada

PROPER USE OF THIS MEDICATION

Consult your doctor if this is your first yeast infection, or if you have a second yeast infection in less than 2 months after treating a prior infection.

Usual dose:

Adults (≥12 years old): Take CANESORAL® by mouth as an one-time only dose, with or without food, or as directed by your doctor. DO NOT take more than one dose for this infection. If your symptoms have not improved within 3 days and disappeared in 7 days, contact your doctor.

Clearing a yeast infection does take time. Although CANESORAL® is taken only once, CANESORAL® therapy does not cure the infection in just one day, the medication remains active in your body for several days. Most patients can expect to see symptom relief begin within 24 hours after taking the capsule. As CANESORAL® works to cure the infection, symptoms will lessen and eventually disappear.

Overdose:

In case of accidental overdose call a doctor or hospital emergency department or poison control centre immediately, even if there are no symptoms.

SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

The most common side effects in clinical studies were headache, nausea, abdominal pain, and diarrhea. Most reported side effects were mild to moderate in nature.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Stop use and contact a doctor or pharmacist if you: develop skin eruptions, experience new rash or irritations or allergy symptoms such as hives. Rarely, severe allergic reactions (swelling of face, eyes, mouth, hands and feet) have occurred.

HOW TO STORE IT

Store the product at room temperature between 15-30 °C
Keep out of reach of children.

REPORTING SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information:

3 ways to report:

- Online at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeffect/index-eng.php>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<http://hc-sc.ca/dhp-mps/medeff/index-eng.php>).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.bayer.ca>

This leaflet was prepared by Bayer Inc. Last Revised: January 27, 2015

Bayer

® TM/MC see www.bayer.ca/tm-mc

Bayer Inc. Mississauga ON L4W 5R6

PART III: CONSUMER INFORMATION
CANESORAL® COMBI-PAK

CANESORAL®

Fluconazole Capsule 150 mg

CANESTEN® EXTERNAL CREAM

Clotrimazole Cream 1%

This leaflet is part III of a three-part "Product Monograph" published when CanesOral® Combi-Pak was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CanesOral® Combi-Pak. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

CanesOral® Combi-Pak is indicated for the treatment of vaginal yeast (fungal) infections. It can be taken anytime, anywhere to relieve the itching, burning, and discharge associated with vaginal yeast infections. CanesOral® is a clinically proven, effective single-dose cure for most vaginal yeast infections that starts to work in 1 day.

What is a Yeast Infection

A "yeast infection" may occur any time there is an overgrowth of yeast organisms in the vagina. The vagina normally has bacteria and yeast organisms present. Under some conditions, the number of yeast organisms rises, irritating the tissues of the vagina and vaginal opening.

Conditions that make this more likely to occur:

- illness
- use of antibiotics
- changes in hormone levels
- pregnancy
- use of oral contraceptive pills
- just before a woman's period
- diabetes
- hot humid weather
- continuous use of panty liners
- tight, non-breathing clothing
- nylon underwear, pantyhose, wet bathing suits or damp workout wear
- perfumed soaps, bubble baths or douching may

cause vaginal irritation and upset the normal balance

Refrain from vaginal intercourse when you have a yeast infection to avoid infecting your partner and to minimize additional discomfort. If your partner has any genital itching, redness or discomfort, they should talk to their doctor and mention that you are treating a yeast infection.

When a "yeast infection" occurs, the body responds with:

- an increase in vaginal secretions
- secretions are generally thick and sticky (cheesy or curd-like, similar to cottage cheese), but odourless
- secretions are irritating to the tissues of the vaginal area
- itching, redness, and swelling of vaginal area
- red spots or sores may develop, especially if the area has been scratched
- soreness in the vagina
- pain during sexual relations

What it does:

CANESORAL® Combi-Pak is an antifungal medication, containing two products. CANESORAL® is an antifungal medication with the active ingredient fluconazole, which works by stopping the growth of the fungi that cause vaginal yeast infections. CANESTEN® External Cream is also an antifungal medication with the active ingredient clotrimazole, which works by relieving the external irritation associated with a yeast infection.

When it should not be used:

Do not use if you are:

- pregnant
- nursing
- allergic to fluconazole, related azoles (e.g. clotrimazole / miconazole) or other ingredients in the product
- taking allergy drugs (e.g. astemizole* / terfenadine*)
- taking cisapride*

* not marketed in Canada

What the medicinal ingredient is:

Fluconazole 150mg (Oral Capsule)

Clotrimazole 1% w/w (Cream)

What the important nonmedicinal ingredients are:

Oral Capsule: colloidal silicon dioxide, D&C Red #7, gelatin, lactose monohydrate, magnesium stearate, pregelatinized starch, propylene glycol, shellac, sodium laurel sulphate and titanium dioxide.

External Cream: benzyl alcohol, cetostearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, sorbitan monostearate, water.

What dosage forms it comes in:

CANESORAL® is available in single-dose foil blister. Each capsule contains 150 mg of fluconazole.

Canesten® External Cream is available in tubes of 10g and contains clotrimazole 1% w/w in a vanishing cream base.

WARNINGS AND PRECAUTIONS

BEFORE USING CANESORAL® COMBI-PAK talk to your doctor or pharmacist if:

- you are having your first yeast infection
- your yeast infection returns in less than 2 months
- you have frequent vaginal infections
- you are at increased risk for sexually transmitted diseases, have multiple sexual partners or change partners often
- you have heart disease
- using in children less than 12 years old

If you could become pregnant while taking CANESORAL®, you should consider using a reliable means of contraception, because the possible effects of this medication on a developing fetus are not known. Canesten Cream reduces the effectiveness of latex condoms and diaphragms. Their use is not recommended during Canesten therapy and for 3 days afterwards. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases.

Yeast infections do not cause:

- Fever
- Chills
- Abdominal pain
- Nausea
- Vomiting

- Diarrhea
- Pain upon urination
- Unexplained pain in your lower back or either shoulder
- Foul-smelling discharge

Consult your doctor immediately if you have these symptoms, as they could be signs of a more serious condition.

INTERACTIONS WITH THIS MEDICATION

BEFORE you use CANESORAL® talk to your doctor or pharmacist if you are taking any other drug especially drugs for:

- AIDS/HIV (zidovudine)
- Allergies (asemizole*, tefenadine*)
- Asthma (theophylline)
- Antibiotics (rifabutin, rifampicin)
- Blood Thinners. (warfarin)
- Diabetes (glyburide, glipizide, tolbutamide)
- Diuretics (hydrochlorothiazide)
- Epilepsy (phenytoin)
- Immune System suppression (cyclosporine, tacrolimus, sirolimus)
- Stomach (cimetidine, cisapride*)
- Sedation (midazolam, triazolam)

* not marketed in Canada

PROPER USE OF THIS MEDICATION

Consult your doctor if this is your first yeast infection, or if you have a second yeast infection in less than 2 months after treating a prior infection.

Usual dose:

Adults (≥12 years old): Take CANESORAL® by mouth as an one-time only dose, with or without food, or as directed by your doctor. DO NOT take more than one dose for this infection. If your symptoms have not improved within 3 days and disappeared in 7 days, contact your doctor.

In addition, a small amount of CANESTEN® External Cream may be applied to the opening of the vagina to help provide extra relief of external symptoms while the oral medication is working to cure the infection. Squeeze a small amount of cream onto your finger and gently spread over the irritated vaginal area. Use once or twice a day and only during the period when external

symptoms are present, to a maximum of 7 days.

Clearing a yeast infection does take time. Although CANESORAL® is taken only once, CANESORAL® ORAL therapy does not cure the infection in just one day, the medication remains active in your body for several days. Most patients can expect to see symptom relief begin within 24 hours after taking the capsule. As CANESORAL® works to cure the infection, symptoms will lessen and eventually disappear.

Overdose:

In case of accidental overdose call a doctor or hospital emergency department or poison control centre immediately, even if there are no symptoms.

SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

The most common side effects in clinical studies for CanesOral® were headache, nausea, abdominal pain, and diarrhea. Most reported side effects were mild to moderate in nature. Infrequent side effects for Canesten® External Cream may include a temporary increase in irritation including redness, itching and burning.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Stop use and contact a doctor or pharmacist if you: develop skin eruptions, experience new rash or irritations or allergy symptoms such as hives. Rarely, severe allergic reactions (swelling of face, eyes, mouth, hands and feet) have occurred.

HOW TO STORE IT

Store the product at room temperature between 15-30 °C. Keep out of reach of children.

REPORTING SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](http://hcc-sc.gc.ca/dhp-mps/medeff/index-eng.php) (<http://hcc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by
 - Fax to 1-866-678-6789 toll-free, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://hcc-sc.gc.ca/dhp-mps/medeff/index-eng.php) (<http://hcc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.bayer.ca>

This leaflet was prepared by Bayer Inc. Last Revised: January 27, 2015

Bayer

® TM/MC see www.bayer.ca/tm-mc

Bayer Inc. Mississauga ON L4W 5R6