

PART III: CONSUMER INFORMATION

Canesten® 6 DAY Internal Cream 1% Clotrimazole vaginal cream - Antifungal

This leaflet is part III of a three-part "Product Monograph" published when CANESTEN® 6 DAY Internal Cream was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CANESTEN® 6 DAY Internal Cream. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

CANESTEN® 6 DAY Internal Cream is used to treat vaginal yeast infections.

CANESTEN® can cure most vaginal yeast infections. Even though the symptoms of an infection may be relieved in only a few hours or days, you should use CANESTEN® for a full 6 days. This will decrease the chance of the infection returning.

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 delicate tissues of the vagina and vaginal opening. Conditions that make this more likely to occur are illness and the use of antibiotics (antibiotics do not affect the yeast organism). Changes in hormone levels may also increase the risk of a yeast infection. Changes that can occur during pregnancy, with the use of oral contraceptive pills, or just before a woman's period, may all increase the risk of a vaginal yeast infection. Some diseases, such as diabetes, can also make a person more susceptible. Even such things as hot humid weather, continuous use of panty liners, or tight, non-breathing clothing may increase a woman's chances of developing a yeast infection. These infections are not usually transmitted through sexual relations, even though a small percentage of male partners do have infections at the same time.

How do I know if I have a "yeast infection"?

When a "yeast infection" occurs, the body responds with an increase in vaginal secretions. These secretions are generally thick and sticky, but odourless. These are often referred to as "cheesy" or "curd-like" because of their similarity to cottage cheese. These secretions are irritating to the tissues of the vaginal area, causing intense itching, redness, and swelling. Sometimes red spots or sores may develop, especially if the area has been scratched in response to the itching. Soreness in the vagina, discomfort when passing urine and pain during sexual relations is common.

What it does:

CANESTEN® is an antifungal that kills the overgrowth of yeast organisms that cause the infection.

When it should not be used:

Do not use CANESTEN® 6 DAY Internal Cream:

- if you are allergic to clotrimazole or any ingredient in the formulation.
- in girls less than 12 years of age unless advised by a physician.

What the medicinal ingredient is:

Clotrimazole 1% w/w

What the important nonmedicinal ingredients are:

Benzyl alcohol, cetostearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, sorbitan monostearate, water.

What dosage forms it comes in:

Vaginal Cream: 1%

WARNINGS AND PRECAUTIONS

BEFORE you use CANESTEN® 6 DAY Internal Cream talk to your doctor or pharmacist if:

- You are at increased risk for sexually transmitted diseases (e.g. HIV-AIDS), have multiple sexual partners or change partner often
- You have diabetes
- This is your first yeast infection
- You have frequent vaginal infections, or if your yeast infection returns in less than 2 months
- you are pregnant, think you are, or are nursing

CANESTEN® cream is for vaginal use only.

Do not use CANESTEN® if you have abdominal pain, fever or a foul-smelling vaginal discharge. If these symptoms are present, you could have a more serious condition and should consult your physician immediately.

Do not use tampons, intravaginal douches or other vaginal products while using this product.

Yeast infections do not cause fevers, chills, nausea, vomiting, diarrhoea, back pain, shoulder pain or vaginal haemorrhaging. If these symptoms are present, or if the vaginal discharge is foul-smelling, a more serious condition may be present and you should consult your physician immediately.

If there is no improvement in your symptoms in 3 days or if they have not disappeared within 7 days, you might not have a vaginal yeast infection. Discontinue treatment and contact your physician.

Contact your physician if symptoms worsen.

Avoid contact with eyes; if this happens, rinse thoroughly with water.

If CANESTEN® is accidentally swallowed, contact your local emergency room or Poison Control Centre immediately.

If you have any questions about CANESTEN® or vaginal infections, contact your pharmacist or physician.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with CANESTEN® 6 DAY Internal Cream include:

- tacrolimus/sirolimus (immunosuppressant)

CANESTEN® may reduce the effectiveness of some birth control methods, such as condoms, diaphragms, or vaginal spermicides. This effect is temporary and occurs only during treatment.

PROPER USE OF THIS MEDICATION

Usual dose:

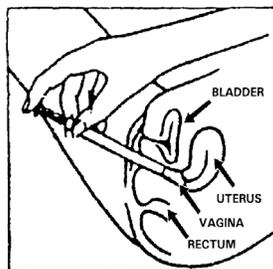
CANESTEN® is inserted high into the vagina once a day (preferably at bedtime) for 6 consecutive days. Sufficient cream is provided for 6 intravaginal applications. Extra cream is supplied for use in relieving the external itching and burning sometimes associated with a vaginal yeast infection. CANESTEN® is only for use in the vagina and should never be taken by mouth. Treatment during the menstrual period should not be performed. The treatment should be finished before the onset of menstruation. While you may have sexual relations during treatment with CANESTEN®, most couples wait until treatment has finished as your partner could become infected.

Filling the Applicator:

Remove the cap from the tube of CANESTEN® and reverse it to puncture the safety seal over the end of the tube. To fill the applicator, screw the open end of the applicator on the end of the tube. Gently squeeze the tube. The plunger will rise as cream enters the applicator. When the plunger stops, the proper amount of CANESTEN® has been pushed into the applicator and the applicator may be removed. Replace the cap and roll up the tube from the bottom so that the tube will be ready for the next use.

Inserting the Medication:

CANESTEN® 6 DAY Internal Cream is inserted into the vagina in much the same way as a tampon. Stand, squat, or lie on your back in a comfortable position. Insert the filled applicator into the vagina as far as it will comfortably go. Holding the barrel of the applicator steady, gently depress the plunger until it stops. This will release the medication high in the vagina where it will be most effective. Remove the applicator.



Using the Cream Externally:

A small amount of CANESTEN® cream may be applied to the opening of the vagina to help provide extra relief of external symptoms. Squeeze a small amount of cream onto your finger and gently spread over the irritated vaginal area. Use the cream once or twice a day and only during the period when external symptoms are present, to a maximum of 7 days.

Disposing of the Applicator:

The CANESTEN® vaginal applicator is recyclable where facilities exist.

Overdose:

In case of drug overdose, call a poison control centre or get medical help right away even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If you experience a rash or new irritation while using the product, discontinue use and contact your doctor.

This is not a complete list of side effects. For any unexpected effects while taking CANESTEN® 6 DAY Internal Cream, contact your doctor or pharmacist.

HOW TO STORE IT

Keep CANESTEN® and all other medications out of the reach of children.

Store at room temperature between 15°C and 30°C

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](#);
- 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 1908C
Ottawa, ON K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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: www.bayer.ca
This leaflet was prepared by Bayer Inc., Mississauga ON L4W 5R6

Last Revised: October 23, 2018

® TM see www.bayer.ca/tm-mc

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PART III: CONSUMER INFORMATION**CANESTEN® 3 DAY Internal Cream
2% Clotrimazole vaginal cream - Antifungal**

This leaflet is part III of a three-part "Product Monograph" published when CANESTEN® 3 DAY Internal Cream was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CANESTEN® 3 DAY Internal Cream. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

CANESTEN® 3 DAY Internal Cream is used to treat vaginal yeast infections.

CANESTEN® can cure most vaginal yeast infections. Even though the symptoms of an infection may be relieved in only a few hours or days, you should use CANESTEN® for a full 3 days. This will decrease the chance of the infection returning.

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 delicate tissues of the vagina and vaginal opening. Conditions that make this more likely to occur are illness and the use of antibiotics (antibiotics do not affect the yeast organism). Changes in hormone levels may also increase the risk of a yeast infection. Changes that can occur during pregnancy, with the use of oral contraceptive pills, or just before a woman's period, may all increase the risk of a vaginal yeast infection. Some diseases, such as diabetes, can also make a person more susceptible. Even such things as hot humid weather, continuous use of panty liners, or tight, non-breathing clothing may increase a woman's chances of developing a yeast infection. These infections are not usually transmitted through sexual relations, even though a small percentage of male partners do have infections at the same time.

How do I know if I have a "yeast infection"?

When a "yeast infection" occurs, the body responds with an increase in vaginal secretions. These secretions are generally thick and sticky, but odourless. These are often referred to as "cheesy" or "curd-like" because of their similarity to cottage cheese. These secretions are irritating to the tissues of the vaginal area, causing intense itching, redness, and swelling. Sometimes red spots or sores may develop, especially if the area has been scratched in response to the itching. Soreness in the vagina, discomfort when passing urine and pain during sexual relations is common.

What it does:

CANESTEN® is an antifungal that kills the overgrowth of yeast organisms that cause the infection.

When it should not be used:

Do not use CANESTEN® 3 DAY Internal Cream:

- if you are allergic to clotrimazole or any ingredient in the

formulation

- in girls less than 12 years of age unless advised by a physician.

What the medicinal ingredient is:

Clotrimazole 2% w/w

What the important nonmedicinal ingredients are:

Benzyl alcohol, cetostearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, sorbitan monostearate, water.

What dosage forms it comes in:

Vaginal Cream: 2%

WARNINGS AND PRECAUTIONS**BEFORE you use CANESTEN® 3 DAY Internal Cream talk to your doctor or pharmacist if:**

- You are at increased risk for sexually transmitted diseases (e.g. HIV-AIDS), have multiple sexual partners or change partner often
- You have diabetes
- This is your first yeast infection
- If you have frequent vaginal infections, or if your yeast infection returns in less than 2 months
- you are pregnant, think you are, or are nursing

CANESTEN® cream is for vaginal use only.

Do not use CANESTEN® if you have abdominal pain, fever or a foul-smelling vaginal discharge. If these symptoms are present, you could have a more serious condition and should consult your physician immediately.

Do not use tampons, intravaginal douches or other vaginal products while using this product.

Yeast infections do not cause fevers, chills, nausea, vomiting, diarrhoea, back pain, shoulder pain or vaginal haemorrhaging. If these symptoms are present, or if the vaginal discharge is foul-smelling, a more serious condition may be present and you should consult your physician immediately.

If there is no improvement in your symptoms in 3 days or if they have not disappeared within 7 days, you might not have a vaginal yeast infection. . Discontinue treatment and contact your physician.

Contact your physician if symptoms worsen.

Avoid contact with eyes; if this happens rinse thoroughly with water.

If CANESTEN® is accidentally swallowed, contact your local emergency room or Poison Control Centre immediately.

If you have any questions about CANESTEN® or vaginal infections, contact your pharmacist or physician.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with CANESTEN® 3 DAY Internal Cream include:

- tacrolimus/sirolimus (immunosuppressant)

CANESTEN® may reduce the effectiveness of some birth control methods, such as condoms, diaphragms, or vaginal spermicides. This effect is temporary and occurs only during treatment.

PROPER USE OF THIS MEDICATION

Usual dose:

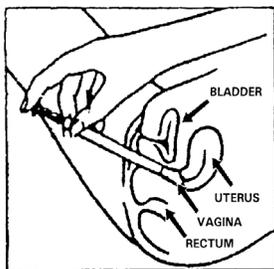
CANESTEN® cream is inserted high into the vagina once a day (preferably at bedtime) for 3 consecutive days. Sufficient cream is provided for 3 intravaginal applications. Extra cream is supplied for use in relieving the external itching and burning sometimes associated with a vaginal yeast infection. CANESTEN® is only for use in the vagina and should never be taken by mouth. Treatment during the menstrual period should not be performed. The treatment should be finished before the onset of menstruation. While you may have sexual relations during treatment with CANESTEN®, most couples wait until treatment has finished as your partner could become infected.

Filling the Applicator:

Remove the cap from the tube of CANESTEN® and reverse it to puncture the safety seal over the end of the tube. To fill the applicator, screw the open end of the applicator on the end of the tube. Gently squeeze the tube. The plunger will rise as cream enters the applicator. When the plunger stops, the proper amount of CANESTEN® has been pushed into the applicator and the applicator may be removed. Replace the cap and roll up the tube from the bottom so that the tube will be ready for the next use.

Inserting the Medication:

CANESTEN® cream is inserted into the vagina in much the same way as a tampon. Stand, squat, or lie on your back in a comfortable position. Insert the filled applicator into the vagina as far as it will comfortably go. Holding the barrel of the applicator steady, gently depress the plunger until it stops. This will release the medication high in the vagina where it will be most effective. Remove the applicator.



Using the Cream Externally:

A small amount of CANESTEN® cream may be applied to the opening of the vagina to help provide extra relief of external symptoms. Squeeze a small amount of cream onto your finger and gently spread over the irritated vaginal area. Use the cream once or twice a day and only during the period when external symptoms are present, to a maximum of 7 days.

Disposing of the Applicator:

The CANESTEN® vaginal applicator is recyclable where facilities exist.

Overdose:

In case of drug overdose, call a poison control centre or get medical help right away even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If you experience a rash or new irritation while using the product, discontinue use and contact your doctor.

This is not a complete list of side effects. For any unexpected effects while taking CANESTEN® 3 DAY Internal Cream, contact your doctor or pharmacist.

HOW TO STORE IT

Keep CANESTEN® and all other medications out of the reach of children.

Store at room temperature between 15°C and 30°C

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](#);
- 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 1908C
Ottawa, ON K1A 0K9 Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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.

Mississauga ON L4W 5R6

Last Revised: October 23, 2018

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PART III: CONSUMER INFORMATION**CANESTEN® 1 DAY Internal Cream
10% Clotrimazole vaginal cream - Antifungal**

This leaflet is part III of a three-part "Product Monograph" published when CANESTEN® 1 DAY Internal Cream was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CANESTEN® 1 DAY Internal Cream. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

CANESTEN® 1 DAY Internal Cream (pre-filled applicator) is used to treat vaginal yeast infections. CANESTEN® can cure most vaginal yeast infections and symptomatic relief can occur in a few hours or days.

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 delicate tissues of the vagina and vaginal opening. Conditions that make this more likely to occur are illness and the use of antibiotics (antibiotics do not affect the yeast organism). Changes in hormone levels may also increase the risk of a yeast infection. Changes that can occur during pregnancy, with the use of oral contraceptive pills, or just before a woman's period, may all increase the risk of a vaginal yeast infection. Some diseases, such as diabetes, can also make a person more susceptible. Even such things as hot humid weather, continuous use of panty liners, or tight, non-breathing clothing may increase a woman's chances of developing a yeast infection. These infections are not usually transmitted through sexual relations, even though a small percentage of male partners do have infections at the same time.

How do I know if I have a "yeast infection"?

When a "yeast infection" occurs, the body responds with an increase in vaginal secretions. These secretions are generally thick and sticky, but odourless. These are often referred to as "cheesy" or "curd-like" because of their similarity to cottage cheese. These secretions are irritating to the tissues of the vaginal area, causing intense itching, redness, and swelling. Sometimes red spots or sores may develop, especially if the area has been scratched in response to the itching. Soreness in the vagina, discomfort when passing urine and pain during sexual relations is common.

What it does:

CANESTEN® is an antifungal that kills the overgrowth of yeast organisms that cause the infection.

When it should not be used:

Do not use CANESTEN® 1 DAY Internal Cream:

- if you are allergic to clotrimazole or any ingredient in the formulation

- in girls less than 12 years of age unless advised by a physician.

What the medicinal ingredient is:

Clotrimazole 10% w/w

What the important nonmedicinal ingredients are:

Benzyl alcohol, cetostearyl alcohol, cetyl esters wax, isopropyl myristate, polysorbate 60, sorbitan monostearate, water.

What dosage forms it comes in:

Vaginal Cream: 10%

WARNINGS AND PRECAUTIONS

BEFORE you use CANESTEN® 1 DAY Internal Cream talk to your doctor or pharmacist if:

- You are at increased risk for sexually transmitted diseases (e.g. HIV-AIDS), have multiple sexual partners or change partner often.
- You have diabetes
- This is your first yeast infection
- You have frequent vaginal infections, or if your yeast infection returns in less than 2 months
- you are pregnant, think you are, or are nursing.

CANESTEN® cream is for vaginal use only.

Do not use CANESTEN® if you have abdominal pain, fever or a foul-smelling vaginal discharge. If these symptoms are present, you could have a more serious condition and should consult your physician immediately.

Do not use tampons, intravaginal douches or other vaginal products while using this product.

Yeast infections do not cause fevers, chills, nausea, vomiting, diarrhoea, back pain, shoulder pain or vaginal haemorrhaging. If these symptoms are present, or if the vaginal discharge is foul-smelling, a more serious condition may be present and you should consult your physician immediately.

There is no improvement in your symptoms in 3 days or if they have not disappeared within 7 days, you might not have a vaginal yeast infection. Discontinue treatment and contact your physician.

Contact your physician if symptoms worsen.

Avoid contact with eyes; if this happens rinse thoroughly with water.

If CANESTEN® is accidentally swallowed, contact your local emergency room or Poison Control Centre immediately.

If you have any questions about CANESTEN® or vaginal infections, contact your pharmacist or physician.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with CANESTEN® 1 DAY Internal

Cream include:

- tacrolimus/sirolimus (immunosuppressant)

CANESTEN® may reduce the effectiveness of some birth control methods, such as condoms, diaphragms, or vaginal spermicides. This effect is temporary and occurs only during treatment

PROPER USE OF THIS MEDICATION

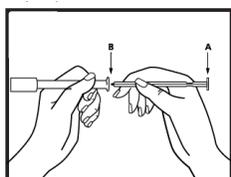
Usual dose:

CANESTEN® cream is inserted high into the vagina once (preferably at bedtime). Sufficient cream is provided for 1 intravaginal application. CANESTEN® cream is only for use in the vagina and should never be taken by mouth. Treatment during the menstrual period should not be performed. The treatment should be finished before the onset of menstruation. While you may have sexual relations during treatment with CANESTEN®, most couples wait until treatment has finished as your partner could become infected.

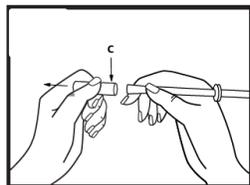
Using the Applicator:

The applicator supplied with this package should be used to ensure proper placement of the vaginal cream high in the vagina preferably at bedtime, where it will provide the most benefit. To use the applicator:

1. Remove the applicator from the package. Keeping the cap in place, insert plunger A into barrel of cream applicator B.

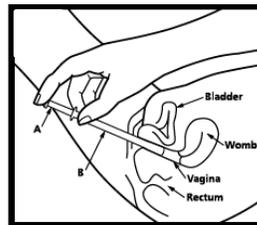


2. Twist and pull to remove cap C. Be careful not to press the plunger in any further before you have inserted the applicator into the vagina.



Inserting the Medication:

CANESTEN® cream (pre-filled applicator) is inserted into the vagina in much the same way as a tampon. Stand, squat, or lie on your back in a comfortable position. Insert the pre-filled applicator into the vagina as far as it will comfortably go. Holding the barrel of the applicator steady, gently depress the plunger until it stops. This will release the medication high in the vagina where it will be most effective. Remove the applicator.



Disposing of the Applicator:

The CANESTEN® vaginal applicator is recyclable where facilities exist.

Overdose:

In case of drug overdose, call a poison control centre or get medical help right away even if there are no symptoms

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If you experience a rash or new irritation while using the product, discontinue use and contact your doctor.

This is not a complete list of side effects. For any unexpected effects while taking CANESTEN® 1 DAY Internal Cream, contact your doctor or pharmacist.

HOW TO STORE IT

Keep CANESTEN® and all other medications out of the reach of children.

Store at room temperature between 15°C and 30°C

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:

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MORE INFORMATION

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

www.bayer.ca

This leaflet was prepared by Bayer Inc., Mississauga ON L4W
5R6

Last Revised: October 23, 2018

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PART III: CONSUMER INFORMATION

CANESTEN® Combi 1 DAY Internal + External Creams 10% Clotrimazole vaginal cream + 1% Clotrimazole External Cream- Antifungal

This leaflet is part III of a three-part "Product Monograph" published when CANESTEN® Combi 1 DAY Internal + External Creams was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CANESTEN® Combi 1 DAY Internal + External Creams. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

CANESTEN® can cure most vaginal yeast infections. The applicator filled with CANESTEN® cream is used to treat the vaginal yeast infection while the tube of CANESTEN® cream is used to externally relieve the itching associated with your vaginal yeast infection. The external cream should only be used during the time when external symptoms are present and for no longer than 7 days.

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 delicate tissues of the vagina and vaginal opening. Conditions that make this more likely to occur are illness and the use of antibiotics (antibiotics do not affect the yeast organism). Changes in hormone levels may also increase the risk of a yeast infection. Changes that can occur during pregnancy, with the use of oral contraceptive pills, or just before a woman's period, may all increase the risk of a vaginal yeast infection. Some diseases, such as diabetes, can also make a person more susceptible. Even such things as hot humid weather, continuous use of panty liners, or tight, non-breathing clothing may increase a woman's chances of developing a yeast infection. These infections are not usually transmitted through sexual relations, even though a small percentage of male partners do have infections at the same time.

How do I know if I have a "yeast infection"?

When a "yeast infection" occurs, the body responds with an increase in vaginal secretions. These secretions are generally thick and sticky, but odourless. These are often referred to as "cheesy" or "curd-like" because of their similarity to cottage cheese. These secretions are irritating to the tissues of the vaginal area, causing intense itching, redness, and swelling. Sometimes red spots or sores may develop, especially if the area has been scratched in response to the itching. Soreness in the vagina, discomfort when passing urine and pain during sexual relations is common.

What it does:

CANESTEN® is an antifungal that kills the overgrowth of yeast organisms that cause the infection.

When it should not be used:

Do not use CANESTEN® Combi 1 DAY Internal + External Creams:

- if you are allergic to clotrimazole or any ingredient in the formulation
- in girls less than 12 years of age unless advised by a physician

What the medicinal ingredient is:

The prefilled applicator contains Clotrimazole 10% w/w
The tube contains Clotrimazole 1% w/w

What the important nonmedicinal ingredients are:

Prefilled Applicator: benzyl alcohol, cetostearyl alcohol, cetyl esters wax, isopropyl myristate, polysorbate 60, sorbitan monostearate, water.

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

What dosage forms it comes in:

Vaginal Cream: 10%

External Cream: 1%

WARNINGS AND PRECAUTIONS

BEFORE you use CANESTEN® Combi 1 DAY Internal + External Creams talk to your doctor or pharmacist if:

- You are at increased risk for sexually transmitted diseases (e.g. HIV-AIDS), have multiple sexual partners or change partner often
- You have diabetes
- This is your first yeast infection
- You have frequent vaginal infections, or if your yeast infection returns in less than 2 months
- You are pregnant, think you are, or are nursing.

CANESTEN® cream is for vaginal use only.

Do not use CANESTEN® if you have abdominal pain, fever or a foul-smelling vaginal discharge. If these symptoms are present, you could have a more serious condition and should consult your physician immediately.

Do not use tampons, intravaginal douches or other vaginal products while using this product.

Yeast infections do not cause fevers, chills, nausea, vomiting, diarrhoea, back pain, shoulder pain or vaginal haemorrhaging. If these symptoms are present, or if the vaginal discharge is foul-smelling, a more serious condition may be present and you should consult your physician immediately.

If there is no improvement in your symptoms in 3 days or if they have not disappeared within 7 days, you might not have a vaginal yeast infection. . Discontinue treatment and contact your physician.

Contact your physician if symptoms worsen.

Avoid contact with eyes; if this happens rinse thoroughly with water.

If CANESTEN® is accidentally swallowed, contact your local emergency room or Poison Control Centre immediately.

If you have any questions about CANESTEN® or vaginal infections, contact your pharmacist or physician.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with CANESTEN® Combi 1 DAY Internal + External Creams include:

- tacrolimus/sirolimus (immunosuppressant)

CANESTEN® may reduce the effectiveness of some birth control methods, such as condoms, diaphragms, or vaginal spermicides. This effect is temporary and occurs only during treatment.

PROPER USE OF THIS MEDICATION

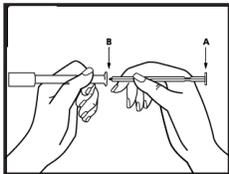
Usual dose:

CANESTEN® cream (pre-filled applicator) is placed high into the vagina once (preferably at bedtime). CANESTEN® vaginal and CANESTEN® external cream are only for use in the vagina and should never be taken by mouth. Treatment during the menstrual period should not be performed. The treatment should be finished before the onset of menstruation. While you may have sexual relations during treatment with CANESTEN®, most couples wait until treatment has finished as your partner could become infected.

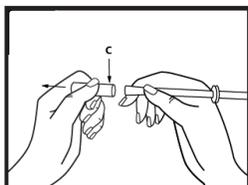
Using the Applicator:

The applicator supplied with this package should be used to ensure proper placement of the vaginal cream high in the vagina preferably at bedtime, where it will provide the most benefit. To use the applicator:

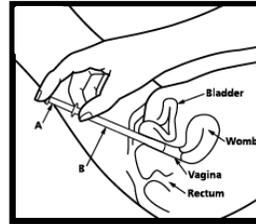
1. Remove the applicator from the package. Keeping the cap in place, insert plunger A into barrel of cream applicator B.



2. Twist and pull to remove cap C. Be careful not to press the plunger in any further before you have inserted the applicator into the vagina.



Inserting the Medication:



CANESTEN® cream (pre-filled applicator) is inserted into the vagina in much the same way as a tampon. Stand, squat, or lie on your back in a comfortable position. Insert the pre-filled applicator into the vagina as far as it will comfortably go. Holding the barrel of the applicator steady, gently depress the plunger until it stops. This will release the medication high in the vagina where it will be most effective. Remove the applicator.

Using the External Cream:

A small amount of Canesten external cream may be applied to the opening of the vagina to help provide extra relief of external symptoms. Squeeze a small amount of cream onto your finger and gently spread over the irritated area of the vulva. Use only once or twice a day and only during the period when external symptoms are present, to a maximum of 7 days.

Disposing of the Applicator:

The CANESTEN® vaginal applicator is recyclable where facilities exist.

Overdose:

In case of drug overdose, call a poison control centre or get medical help right away even if there are no symptoms

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If you experience a rash or new irritation while using the product, discontinue use and contact your doctor.

This is not a complete list of side effects. For any unexpected effects while taking CANESTEN® Combi 1 DAY Internal + External Creams, contact your doctor or pharmacist.

HOW TO STORE IT

Keep CANESTEN® and all other medications out of the reach of children.

Store at room temperature between 15°C and 30°C

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](#);
- 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 1908C
Ottawa, ON K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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:

www.bayer.ca

This leaflet was prepared by Bayer Inc., Mississauga ON L4W 5R6

Last Revised: October 23, 2018

® TM see www.bayer.ca/tm-mc

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PART III: CONSUMER INFORMATION

CANESTEN® Combi 1 DAY ComforTAB® + External Cream
500 mg Clotrimazole Vaginal Tablet + 1% Clotrimazole External Cream- Antifungal

This leaflet is part III of a three-part "Product Monograph" published when CANESTEN® Combi 1 DAY ComforTAB® + External Cream was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CANESTEN® Combi 1 DAY ComforTAB® + External Cream. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

CANESTEN® can cure most vaginal yeast infections. The CANESTEN® vaginal tablet is used to treat the vaginal infection while the CANESTEN® cream is used externally to relieve the itching associated with your vaginal yeast infection. The cream should be used only during the time when external symptoms are present and for no longer than 7 days.

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 delicate tissues of the vagina and vaginal opening. Conditions that make this more likely to occur are illness and the use of antibiotics (antibiotics do not affect the yeast organism). Changes in hormone levels may also increase the risk of a yeast infection. Changes that can occur during pregnancy, with the use of oral contraceptive pills, or just before a woman's period, may all increase the risk of a vaginal yeast infection. Some diseases, such as diabetes, can also make a person more susceptible. Even such things as hot humid weather, continuous use of panty liners, or tight, non-breathing clothing may increase a woman's chances of developing a yeast infection. These infections are not usually transmitted through sexual relations, even though a small percentage of male partners do have infections at the same time.

How do I know if I have a "yeast infection"?

When a "yeast infection" occurs, the body responds with an increase in vaginal secretions. These secretions are generally thick and sticky, but odourless. These are often referred to as "cheesy" or "curd-like" because of their similarity to cottage cheese. These secretions are irritating to the tissues of the vaginal area, causing intense itching, redness, and swelling. Sometimes red spots or sores may develop, especially if the area has been scratched in response to the itching. Soreness in the vagina, discomfort when passing urine and pain during sexual relations is common.

What it does:

CANESTEN® is an antifungal that kills the overgrowth of yeast organisms that cause the infection-

When it should not be used:

Do not use CANESTEN® Combi 1 DAY ComforTAB® + External Cream:

- if you are allergic to clotrimazole or any ingredient in the formulation
- in girls less than 12 years of age unless advised by a physician.

What the medicinal ingredient is:

Clotrimazole 500mg
 Clotrimazole 1% w/w

What the important nonmedicinal ingredients are:

Vaginal Tablet: calcium lactate, colloidal silicon dioxide, crospovidone, hydroxypropyl methylcellulose, lactic acid, lactose, magnesium stearate, microcrystalline cellulose, maize starch
 Cream: benzyl alcohol, cetostearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, sorbitan monostearate, water.

What dosage forms it comes in:

Vaginal Tablet: 500mg
 External Cream: 1%

WARNINGS AND PRECAUTIONS

BEFORE you use CANESTEN® Combi 1 DAY ComforTAB® + External Cream talk to your doctor or pharmacist if:

- You are at increased risk for sexually transmitted diseases (e.g. HIV-AIDS), have multiple sexual partners or change partner often
- You have diabetes
- This is your first yeast infection
- You have frequent vaginal infections, or if your yeast infection returns in less than 2 months
- You are pregnant, think you are, or are nursing.

CANESTEN® vaginal tablet is for vaginal use only.
 CANESTEN® cream is for external vaginal use only.

Do not use CANESTEN® if you have abdominal pain, fever or a foul-smelling vaginal discharge. If these symptoms are present, you could have a more serious condition and should consult your physician immediately.

Do not use tampons, intravaginal douches or other vaginal products while using this product.

Yeast infections do not cause fevers, chills, nausea, vomiting, diarrhoea, back pain, shoulder pain or vaginal haemorrhaging. If these symptoms are present, or if the vaginal discharge is foul-smelling, a more serious condition may be present and you should consult your physician immediately.

If there is no improvement in your symptoms in 3 days or if they have not disappeared within 7 days, you might not have a vaginal

yeast infection. . Discontinue treatment and contact your physician.

Contact your physician if symptoms worsen.

Avoid contact with eyes; if this happens rinse thoroughly with water.

If CANESTEN® is accidentally swallowed, contact your local emergency room or Poison Control Centre immediately.

If you have any questions about CANESTEN® or vaginal infections, contact your pharmacist or physician.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with CANESTEN® Combi 1 DAY ComforTAB® + External Cream include:

- tacrolimus/sirolimus (immunosuppressant)

CANESTEN® may reduce the effectiveness of some birth control methods, such as condoms, diaphragms, or vaginal spermicides. This effect is temporary and occurs only during treatment.

PROPER USE OF THIS MEDICATION

Usual dose:

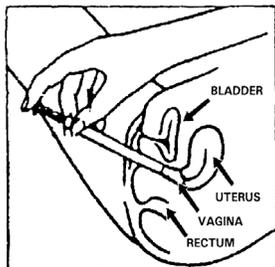
The CANESTEN® vaginal tablet is placed high into the vagina once (preferably at bedtime). CANESTEN® vaginal tablets and CANESTEN® cream are only for use in the vagina and irritated vaginal area and should never be taken by mouth. Treatment during the menstrual period should not be performed. The treatment should be finished before the onset of menstruation. While you may have sexual relations during treatment with CANESTEN®, most couples wait until treatment has finished as your partner could become infected.

Using the Applicator:

The applicator supplied with this package should be used to ensure proper placement of the vaginal tablet high in the vagina, where it will provide the most benefit. To use the applicator, first remove the CANESTEN® vaginal tablet from its protective foil wrapper. Next, pull the applicator's plunger outward until it stops. The vaginal tablet is then placed into the end of the applicator and is ready for use.

Inserting the Medication:

The CANESTEN® vaginal tablet is placed into the vagina in much the same way as a tampon. Stand, squat, or lie on your back in a comfortable position. Insert the loaded applicator into the vagina as far as it will comfortably go. Holding the barrel of the applicator steady, gently depress the plunger until it stops. This will release the medication high in the vagina where it will be most effective. Remove the applicator.



Using the Cream:

A small amount of Canesten cream may be applied to the opening of the vagina to help provide extra relief of external symptoms. 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.

Disposing of the Applicator:

The CANESTEN® vaginal applicator is recyclable where facilities exist.

Overdose:

In case of drug overdose, call a poison control centre or get medical help right away even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If you experience a rash or new irritation while using the product, discontinue use and contact your doctor.

This is not a complete list of side effects. For any unexpected effects while taking CANESTEN® Combi 1 DAY ComforTAB® + External Cream, contact your doctor or pharmacist.

HOW TO STORE IT

Keep CANESTEN® and all other medications out of the reach of children.

Store at room temperature between 15°C and 30°C

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](#);
- 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 1908C
Ottawa, ON K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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:
www.bayer.ca

This leaflet was prepared by Bayer Inc. Mississauga, ON L4W 5R6
Last revised: October 23, 2018

® TM see
www.bayer.ca/tm-mc

PART III: CONSUMER INFORMATION

CANESTEN® Combi 3 DAY ComforTAB™ + External Cream 200 mg Clotrimazole Vaginal Tablet + 1% Clotrimazole External Cream- Antifungal

This leaflet is part III of a three-part "Product Monograph" published when CANESTEN® Combi 3 DAY ComforTAB™ + External Cream was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CANESTEN® Combi 3 DAY ComforTAB™ + External Cream. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

CANESTEN® vaginal tablet is used to treat the vaginal infection while the CANESTEN® cream is used externally to relieve the itching associated with your vaginal yeast infection. The cream should be used only during the time when external symptoms are present and for no longer than 7 days. CANESTEN® can cure most vaginal yeast infections. Even though the symptoms of an infection may be relieved in only a few hours or days, you should use CANESTEN® as directed for a full 3 days. This will decrease the change of the infection returning.

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 delicate tissues of the vagina and vaginal opening. Conditions that make this more likely to occur are illness and the use of antibiotics (antibiotics do not affect the yeast organism). Changes in hormone levels may also increase the risk of a yeast infection. Changes that can occur during pregnancy, with the use of oral contraceptive pills, or just before a woman's period, may all increase the risk of a vaginal yeast infection. Some diseases, such as diabetes, can also make a person more susceptible. Even such things as hot humid weather, continuous use of panty liners, or tight, non-breathing clothing may increase a woman's chances of developing a yeast infection. These infections are not usually transmitted through sexual relations, even though a small percentage of male partners do have infections at the same time.

How do I know if I have a "yeast infection"?

When a "yeast infection" occurs, the body responds with an increase in vaginal secretions. These secretions are generally thick and sticky, but odourless. These are often referred to as "cheesy" or "curd-like" because of their similarity to cottage cheese. These secretions are irritating to the tissues of the vaginal area, causing intense itching, redness, and swelling. Sometimes red spots or sores may develop, especially if the area has been scratched in response to the itching. Soreness in the vagina, discomfort when passing urine and pain during sexual relations is common.

What it does:

To cure a "yeast infection", it is necessary to kill the overgrowth of yeast organisms that cause the infection.

When it should not be used:

Do not use CANESTEN® Combi 3 DAY ComforTAB™ + External Cream:

- if you are allergic to clotrimazole or any ingredient in the formulation
- in girls less than 12 years of age unless advised by a physician.

What the medicinal ingredient is:

Clotrimazole 200mg
Clotrimazole 1% w/w

What the important nonmedicinal ingredients are:

Vaginal Tablet: calcium lactate, colloidal silicon dioxide, crospovidone, hydroxypropyl methylcellulose, lactic acid, lactose monohydrate, magnesium stearate, microcrystalline cellulose, maize starch

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

What dosage forms it comes in:

Vaginal Tablet: 200mg
External Cream: 1%

WARNINGS AND PRECAUTIONS

BEFORE you use CANESTEN® Combi 3 DAY ComforTAB™ + External Cream talk to your doctor or pharmacist if:

- You are at increased risk for sexually transmitted diseases (e.g. HIV-AIDS), have multiple sexual partners or change partner often
- You have diabetes
- This is your first yeast infection
- You have frequent vaginal infections, or if your yeast infection returns in less than 2 months
- You are pregnant, think you are, or are nursing.

CANESTEN® vaginal tablet is for vaginal use only.

CANESTEN® cream is for external vaginal use only.

Do not use CANESTEN® if you have abdominal pain, fever or a foul-smelling vaginal discharge. If these symptoms are present, you could have a more serious condition and should consult your physician immediately.

Do not use tampons, intravaginal douches or other vaginal products while using this product.

Yeast infections do not cause fevers, chills, nausea, vomiting, diarrhoea, back pain, shoulder pain or vaginal haemorrhaging. If these symptoms are present, or if the vaginal discharge is foul-smelling, a more serious condition may be present and you should consult your physician immediately.

If there is no improvement in your symptoms in 3 days or if they have not disappeared within 7 days, you might not have a vaginal yeast infection. . Discontinue treatment and contact your physician.

Contact your physician if symptoms worsen.

Avoid contact with eyes; if this happens rinse thoroughly with water.

If CANESTEN® is accidentally swallowed, contact your local emergency room or Poison Control Centre immediately.

If you have any questions about CANESTEN® or vaginal infections, contact your pharmacist or physician.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Combi 3 DAY ComforTAB™ + External Cream include:

- tacrolimus/sirolimus (immunosuppressant)

CANESTEN® may reduce the effectiveness of some birth control methods, such as condoms, diaphragms, or vaginal spermicides. This effect is temporary and occurs only during treatment.

PROPER USE OF THIS MEDICATION

Usual dose:

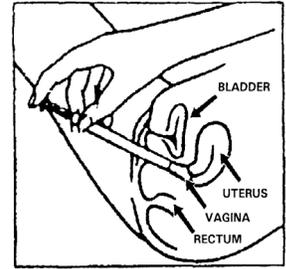
One CANESTEN® vaginal tablet is placed high into the vagina once a day (preferably at bedtime) for 3 consecutive days. CANESTEN® vaginal tablets and CANESTEN® cream are only for use in the vagina and irritated vaginal area and should never be taken by mouth. Treatment during the menstrual period should not be performed. The treatment should be finished before the onset of menstruation. While you may have sexual relations during treatment with CANESTEN®, most couples wait until treatment has finished as your partner could become infected.

Using the Applicator:

The applicator supplied with this package should be used to ensure proper placement of the vaginal tablet high in the vagina, where it will provide the most benefit. To use the applicator, first remove the CANESTEN® vaginal tablet from its protective foil wrapper. Next, pull the applicator's plunger outward until it stops. The vaginal tablet is then placed into the end of the applicator and is ready for use.

Inserting the Medication:

CANESTEN® vaginal tablets are placed into the vagina in much the same way as a tampon. Stand, squat, or lie on your back in a comfortable position. Insert the loaded applicator into the vagina as far as it will comfortably go. Holding the barrel of the applicator steady, gently depress the plunger until it stops. This will release the medication high in the vagina where it will be most effective. Remove the applicator.



Using the Cream:

A small amount of Canesten cream may be applied to the opening of the vagina to help provide extra relief of external symptoms. 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.

Disposing of the Applicator:

The CANESTEN® vaginal applicator is recyclable where facilities exist.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If you experience a rash or new irritation while using the product, discontinue use and contact your doctor.

This is not a complete list of side effects. For any unexpected effects while taking CANESTEN® Combi 3 DAY ComforTAB™+ External Cream, contact your doctor or pharmacist.

HOW TO STORE IT

Keep CANESTEN® and all other medications out of the reach of children.

Store at room temperature between 15°C and 30°C

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](#);
- 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 1908C
Ottawa, ON K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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., Mississauga ON L4W 5R6

Last Revised: October 23, 2018

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PART III: CONSUMER INFORMATION**CANESTEN® External Antifungal Cream
1% Clotrimazole External Cream- Antifungal**

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

ABOUT THIS MEDICATION**What the medication is used for:**

CANESTEN® External Antifungal Cream is used externally to relieve the itching associated with your vaginal yeast infection. The cream should be used only during the time when external symptoms are present and for no longer than 7 days. Use only in conjunction with CANESTEN® Internal Treatments or CanesOral® Capsules.

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 delicate tissues of the vagina and vaginal opening. Conditions that make this more likely to occur are illness and the use of antibiotics (antibiotics do not affect the yeast organism). Changes in hormone levels may also increase the risk of a yeast infection. Changes that can occur during pregnancy, with the use of oral contraceptive pills, or just before a woman's period, may all increase the risk of a vaginal yeast infection. Some diseases, such as diabetes, can also make a person more susceptible. Even such things as hot humid weather, continuous use of panty liners, or tight, non-breathing clothing may increase a woman's chances of developing a yeast infection. These infections are not usually transmitted through sexual relations, even though a small percentage of male partners do have infections at the same time.

How do I know if I have a "yeast infection"?

When a "yeast infection" occurs, the body responds with an increase in vaginal secretions. These secretions are generally thick and sticky, but odourless. These are often referred to as "cheesy" or "curd-like" because of their similarity to cottage cheese. These secretions are irritating to the tissues of the vaginal area, causing intense itching, redness, and swelling. Sometimes red spots or sores may develop, especially if the area has been scratched in response to the itching. Soreness in the vagina, discomfort when passing urine and pain during sexual relations is common.

What it does:

Relieves external vaginal itching, burning and discomfort.

When it should not be used:

Do not use CANESTEN® External Antifungal Cream:

- if you are allergic to clotrimazole or any ingredient in the

formulation

- in girls less than 12 years of age unless advised by a physician.

What the medicinal ingredient is:

Clotrimazole 1% w/w

What the important nonmedicinal ingredients are:

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

What dosage forms it comes in:

External Cream: 1%

WARNINGS AND PRECAUTIONS**BEFORE you use CANESTEN® External Antifungal Cream talk to your doctor or pharmacist if:**

- You are at increased risk for sexually transmitted diseases (e.g. HIV-AIDS), have multiple sexual partners or change partner often
- You have diabetes
- This is your first yeast infection
- You have frequent vaginal infections, or if your yeast infection returns in less than 2 months
- you are pregnant, think you are, or are nursing.

CANESTEN® cream is for external vaginal use only.

Do not use CANESTEN® if you have abdominal pain, fever or a foul-smelling vaginal discharge. If these symptoms are present, you could have a more serious condition and should consult your physician immediately.

Do not use tampons, intravaginal douches or other vaginal products while using this product.

Yeast infections do not cause fevers, chills, nausea, vomiting, diarrhoea, back pain, shoulder pain or vaginal haemorrhaging. If these symptoms are present, or if the vaginal discharge is foul-smelling, a more serious condition may be present and you should consult your physician immediately.

If there is no improvement in your symptoms in 3 days or if they have not disappeared within 7 days, you might not have a vaginal yeast infection. Discontinue treatment and contact your physician.

Contact your physician if symptoms worsen.

Avoid contact with eyes; if this happens rinse thoroughly with water.

If CANESTEN® is accidentally swallowed, contact your local emergency room or Poison Control Centre immediately.

If you have any questions about CANESTEN® or vaginal infections, contact your pharmacist or physician.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with CANESTEN® External Antifungal Cream include:

- tacrolimus/sirolimus (immunosuppressant)

CANESTEN® may reduce the effectiveness of some birth control methods, such as condoms, diaphragms, or vaginal spermicides. This effect is temporary and occurs only during treatment.

PROPER USE OF THIS MEDICATION

Usual dose:

A small amount of Canesten cream may be applied to the opening of the vagina to help provide extra relief of external symptoms. 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.

Overdose:

In case of drug overdose, call a poison control centre or get medical help right away even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If you experience a rash or new irritation while using the product, discontinue use and contact your doctor.

This is not a complete list of side effects. For any unexpected effects while taking CANESTEN® External Antifungal Cream, contact your doctor or pharmacist.

HOW TO STORE IT

Keep CANESTEN® and all other medications out of the reach of children.

Store at room temperature between 15°C and 30°C

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.

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 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator
1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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: www.Bayer.ca

This leaflet was prepared by Bayer Inc. Mississauga, ON L4W 5R6

Last revised: December 5, 2018

® TM see www.bayer.ca/tm-mc

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Bayer

PART III: CONSUMER INFORMATION**CANESTEN® Extra Strength External Antifungal Cream
2% Clotrimazole External Cream - Antifungal**

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

ABOUT THIS MEDICATION**What the medication is used for:**

CANESTEN® Extra Strength External Antifungal Cream is used externally to relieve the itching associated with your vaginal yeast infection. The cream should be used only during the time when external symptoms are present and for no longer than 7 days. Use only in conjunction with CANESTEN® internal treatments or CanesOral®.

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 delicate tissues of the vagina and vaginal opening. Conditions that make this more likely to occur are illness and the use of antibiotics (antibiotics do not affect the yeast organism). Changes in hormone levels may also increase the risk of a yeast infection. Changes that can occur during pregnancy, with the use of oral contraceptive pills, or just before a woman's period, may all increase the risk of a vaginal yeast infection. Some diseases, such as diabetes, can also make a person more susceptible. Even such things as hot humid weather, continuous use of panty liners, or tight, non-breathing clothing may increase a woman's chances of developing a yeast infection. These infections are not usually transmitted through sexual relations, even though a small percentage of male partners do have infections at the same time.

How do I know if I have a "yeast infection"?

When a "yeast infection" occurs, the body responds with an increase in vaginal secretions. These secretions are generally thick and sticky, but odourless. These are often referred to as "cheesy" or "curd-like" because of their similarity to cottage cheese. These secretions are irritating to the tissues of the vaginal area, causing intense itching, redness, and swelling. Sometimes red spots or sores may develop, especially if the area has been scratched in response to the itching. Soreness in the vagina, discomfort when passing urine and pain during sexual relations is common.

What it does:

Relieves external vaginal itching, burning and discomfort.

When it should not be used:

Do not use CANESTEN® Extra Strength External Antifungal Cream:

- if you are allergic to clotrimazole or any ingredient in the formulation
- in girls less than 12 years of age unless advised by a physician.

What the medicinal ingredient is:

Clotrimazole 2% w/w

What the important nonmedicinal ingredients are:

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

What dosage forms it comes in:

External Cream: 2%

WARNINGS AND PRECAUTIONS**BEFORE you use CANESTEN® Extra Strength External Antifungal Cream talk to your doctor or pharmacist if:**

- You are at increased risk for sexually transmitted diseases (e.g. HIV-AIDS), have multiple sexual partners or change partner often
- You have diabetes
- This is your first yeast infection
- You have frequent vaginal infections, or if your yeast infection returns in less than 2 months
- You are pregnant, think you are, or are nursing.

CANESTEN® cream is for external vaginal use only.

Do not use CANESTEN® if you have abdominal pain, fever or a foul-smelling vaginal discharge. If these symptoms are present, you could have a more serious condition and should consult your physician immediately.

Do not use tampons, intravaginal douches or other vaginal products while using this product.

Yeast infections do not cause fevers, chills, nausea, vomiting, diarrhoea, back pain, shoulder pain or vaginal haemorrhaging. If these symptoms are present, or if the vaginal discharge is foul-smelling, a more serious condition may be present and you should consult your physician immediately.

If there is no improvement in your symptoms in 3 days or if they have not disappeared within 7 days, you might not have a vaginal yeast infection. Discontinue treatment and contact your physician.

Contact your physician if symptoms worsen.

Avoid contact with eyes; if this happens rinse thoroughly with water.

If CANESTEN® is accidentally swallowed, contact your local emergency room or Poison Control Centre immediately.

If you have any questions about CANESTEN® or vaginal infections, contact your pharmacist or physician.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with CANESTEN® Extra Strength External Antifungal Cream include:

- tacrolimus/sirolimus (immunosuppressant)

CANESTEN® may reduce the effectiveness of some birth control methods, such as condoms, diaphragms, or vaginal spermicides. This effect is temporary and occurs only during treatment.

PROPER USE OF THIS MEDICATION

Usual dose:

A small amount of Canesten cream may be applied to the opening of the vagina to help provide extra relief of external symptoms. Squeeze a small amount of cream onto your finger and gently spread over the irritated external vaginal area. Use once or twice a day and only during the period when external symptoms are present, to a maximum of 7 days.

Overdose:

In case of drug overdose, call a poison control centre or get medical help right away even if there are no symptoms

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If you experience a rash or new irritation while using the product, discontinue use and contact your doctor.

This is not a complete list of side effects. For any unexpected effects while taking CANESTEN® Extra Strength External Antifungal Cream, contact your doctor or pharmacist.

HOW TO STORE IT

Keep CANESTEN® and all other medications out of the reach of children.

Store at room temperature between 15°C and 30°C

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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>

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