

## PATIENT MEDICATION INFORMATION :

# CANESTEN<sup>®</sup> 1% TOPICAL CREAM

*clotrimazole*

Antifungal Agent

Bayer

*Date of Revision: February 27, 2020*

This leaflet is part III of a three-part "Product Monograph" published when CANESTEN 1% Topical 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% Topical 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% Topical Cream is used for the treatment of athlete's foot, jock itch, ringworm, infected diaper rash and infections of the skin and mucous membranes.

CANESTEN can cure most fungal or yeast infections. Even though the symptoms of your infection may be relieved in only a few days, you should use CANESTEN for the full treatment period.

### What is "athlete's foot"?

"Athlete's foot" is an infection of the foot caused by a fungus. It usually starts between the 3rd, 4th and 5th toes and later can spread to the skin under the toes. There may be itching and burning of the infected areas, and liquid may ooze out. If the toes are spread apart, the skin is usually found to be white, swollen and torn. If the infection spreads beyond the spaces between the toes to the area under the toes and the bottom of the foot, blisters and broken skin are the most common symptoms.

### What is "jock itch"?

"Jock itch" is an infection in the groin area caused by a fungus. It occurs more commonly in males. The first signs of the infection are scaling of the skin, irritation and itching in the groin area. The scaling or rash may affect the upper thighs and sometimes the scrotum. Red, raised lesions may also be found on the scrotum and may extend to the anus.

### What is "ringworm"?

"Ringworm" is a fungal infection of the skin, which may or may not be accompanied by symptoms. If symptoms are present, they usually involve scaling of the skin, crusting and the formation of pink to red lesions with clear centres. The lesions may appear circular with a clear area in the middle. The infection may occur anywhere on the body.

### What is "diaper rash"?

Diaper rash is an inflammation of the skin and is a direct result of wearing diapers. Almost all babies suffer from diaper rash at one time or another. Diaper rash is caused by physical chaffing and chemical attack of the skin by urine and feces left too long in the diaper. Diaper rashes can be infected by yeast, particularly if they persist for more than 3 days. A diaper rash infected by yeast may be recognized by the appearance of bright red skin with scaly edges and contain pinhead sized whitehead usually seen around the main rash and along the inner thighs, which has been diagnosed by a doctor. The skin is sensitive and painful to touch, particularly during urination or a bowel movement.

**What is “tinea versicolor”?**

Tinea versicolor is a common fungal infection in young adults. The most noticeable symptom is patches of skin which are different in colour from the rest of the skin. These patches can be white, brown, or have no pigment. They are usually found on the chest, neck, abdomen, back and occasionally on the face. The skin in the affected areas may have scales, but these are not obvious unless the area is scratched. The condition is often noticed in the summer, because the white areas do not tan, but appear as white "sun-spots" of different sizes. Itching is uncommon and occurs only when the person is hot and sweating.

**What is “candidiasis”?**

Candidiasis is a yeast infection of the skin and mucous membranes. It often appears in the armpits, creases of the neck, the groin, between the toes or buttocks, and beneath large breasts. The usual symptoms are burning, itching, cracks and scaling of the skin with small, red lesions.

**How can I help prevent “athlete's foot”?**

Bathe your feet regularly with soap and water. Towel-dry your feet, paying special attention to the area between the toes. Let your feet air-dry for 5 to 10 minutes. Wear absorbent socks made of 100% cotton or wool and well-fitting shoes that allow air circulation. Change your socks and shoes frequently. Avoid walking in bare feet at health clubs, public pools and other wet areas.

**How can I help prevent “diaper rash”?**

Proper diaper hygiene is the most effective way to prevent diaper rash. Ensure that the baby's diapers are frequently changed and properly and thoroughly cleaned. The diaper area should be cleansed often, using lukewarm water and gently patted dry or air dried before another diaper is put on. Do not use detergents or other laundry products that are not recommended for infant use. Avoid using soaps or commercial wipes that contain irritants if there is a rash present.

**What it does:**

To cure a fungal or yeast infection, it is necessary to kill the overgrowth of organisms that have caused the infection.

**When it should not be used:**

Do not use CANESTEN 1% Topical Cream:

- if you are allergic to any ingredients in this drug
- on children under 2 years of age, unless recommended by a doctor
- for scalp or nail infections

**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:**

Topical Cream: 1%

## WARNINGS AND PRECAUTIONS:

### **BEFORE you use CANESTEN 1% Topical Cream talk to your doctor or pharmacist if:**

- you are pregnant, trying to get pregnant, or breastfeeding

CANESTEN 1% Topical Cream is for topical use only.

For the treatment of diaper rash (yeast infected), use only if your child has a yeast-infected diaper rash diagnosed by a physician. If there is no improvement in the rash after 14 days of treatment with CANESTEN, consult your physician.

For adult treatment, consult your doctor if signs and symptoms of the infection have not resolved after 4 weeks.

Occlusive dressings should not be applied on top of CANESTEN unless directed by a physician. It is noted that diapers would not be considered occlusive dressings because of frequent changes and airings, normal hygiene practices and the use of newer more breathable and absorbent diapers.

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 topical fungal infections, contact your physician or pharmacist.

## INTERACTIONS WITH THIS MEDICATION:

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:

**CHILDREN** (for the treatment of diaper rash secondarily infected with *Candida albicans* and diagnosed by a doctor): Thinly apply and gently massage sufficient CANESTEN 1% Topical Cream into the affected and surrounding skin areas twice daily at diaper change (in the morning and evening).

**ADULTS** (for the treatment of jock itch, athlete's foot and ringworm): Thinly apply and gently massage sufficient CANESTEN 1% Topical Cream into the affected and surrounding skin areas twice daily, in the morning and evening.

Do not cover the medication with a bandage unless advised to do so by your physician.

For the treatment to be completely successful, CANESTEN 1% Topical Cream should be applied regularly and in sufficient quantities. If you miss a dose, do not apply twice as much medication at the next dosing. "Athlete's foot" should be treated for 4 weeks, while "jock itch", "ringworm", "tinea versicolor", "candidiasis", and "infected diaper rash" usually require 2 weeks of treatment.

### **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 irritation while using CANESTEN, discontinue use and contact your physician.

Side effects which can occur include: stinging, burning, rash, itching, irritation, peeling skin, redness, swelling (edema) and allergic reaction with symptoms such as fainting, low blood pressure or hives.

***This is not a complete list of side effects. For any unexpected effects while taking CANESTEN 1% Topical 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

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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](#) 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: [www.bayer.ca](http://www.bayer.ca)

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