

		<i>Canesten Plus CMI</i> 16 May 2016
	<b>Consumer Medicine Information</b>	

# CANESTEN<sup>®</sup> PLUS

## Topical Cream – Clotrimazole 10 mg/g & Hydrocortisone 10 mg/g

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### What is in this Leaflet

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This leaflet answers some common questions about CANESTEN PLUS Clotrimazole and Hydrocortisone Cream.

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

All medicines have risks and benefits. Your pharmacist has weighed the risks of you using CANESTEN PLUS cream against the benefits they expect it will have for you.

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

#### **Keep this leaflet with your medicine.**

You may need to read it again.

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### What is CANESTEN PLUS cream used for?

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CANESTEN PLUS cream is used on the skin to treat and soothe inflamed fungal skin conditions such as:

- Tinea pedis (athlete's foot)
- External symptoms of thrush
- Jock itch
- Fungally infected nappy rash
- Ringworm
- Fungal skin rash
- Fungally infected eczema or dermatitis.

CANESTEN PLUS cream is a broad spectrum anti-fungal and anti-inflammatory cream. It contains two active ingredients; clotrimazole and hydrocortisone (as acetate).

Clotrimazole belongs to a group of medicines called imidazole antifungals which are used to treat fungal skin infections. Hydrocortisone is a mild steroid which reduces the swelling, redness and itching associated with inflammation of the skin.

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For conditions without inflammation use an antifungal agent without hydrocortisone, such as Canesten clotrimazole antifungal cream.

This product should only be used in children under 2 years of age (for example, fungal nappy rash) if a doctor has told you to.

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

CANESTEN PLUS is a Pharmacist Only Medicine. This medicine is available without a doctor's prescription, only through your pharmacist.

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## **Before using CANESTEN PLUS Cream**

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### ***When you must not use it***

**Do not use CANESTEN PLUS cream if:**

- 1. you have an allergy to any of the ingredients of CANESTEN PLUS cream listed at the end of this leaflet**
- 2. the skin on the area to be treated is cracked or broken**
- 3. you have a viral skin infection (such as cold sores, shingles or chicken pox)**
- 4. you have other infections of the skin [such as acne, rosacea, perioral dermatitis, lues (syphilis), tuberculosis (which very rarely can present as a skin infection, although normally a disease of the lungs)]**
- 5. you have a reaction of the skin resulting from a vaccination.**

**Do not use CANESTEN PLUS cream just before having a bath, shower or going swimming.**

If you do, you may reduce the effectiveness of CANESTEN PLUS cream.

**Do not use CANESTEN PLUS cream if the packaging is torn or shows signs of tampering.**

**Do not use CANESTEN PLUS cream if the expiry date (EXP) printed on the pack has passed.**

If you use this medicine after the expiry date has passed, it may not work as well.

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

### ***Before you start to use it***

**Consult your doctor or pharmacist first if:**

- 1. You are pregnant or suspect you may be pregnant:**  
Your doctor will discuss with you the risks and benefits of using CANESTEN PLUS while

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you are pregnant. It is preferably to avoid the use of Canesten Plus during the first trimester of pregnancy.

**2. You are breast-feeding:**

Your doctor will discuss with you the risks and benefits of using CANESTEN PLUS while you are breastfeeding.

**3. You have cuts or abrasions at or near the area to be treated:**

The chance of unwanted effects may be increased.

**Tell your doctor or pharmacist if you are allergic to any other medicines, foods, preservatives or dyes.**

***Taking other medicines***

**Tell your doctor or pharmacist if you are using other creams, ointments or lotions or taking any medicine, including any you have bought without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines and CANESTEN PLUS cream may interfere with each other. These medicines may be affected by CANESTEN PLUS cream or may affect how well it works

Your doctor or pharmacist will have more information on medicines to be careful with or avoid while taking CANESTEN PLUS cream.

**How to use CANESTEN PLUS Cream**

**Follow all directions given to you by your doctor or pharmacist carefully. These directions may differ from the information contained in this leaflet.**

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

It is important to use CANESTEN PLUS cream exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well and your skin problem may not improve. Using it more often than you should may not improve your skin problem any faster and may cause or increase side effects.

***How to use it***

Before use, pierce the seal on the tube by inverting the cap over the end of the tube and pressing.

A small amount of CANESTEN PLUS cream should be applied thinly and evenly with gentle rubbing to the affected area(s) twice daily.

***How long to use it***

Use only until inflammation, itching and redness have subsided, and not for more than 7 days (unless a doctor has told you to). Then use a clotrimazole-only cream, such as CANESTEN Clotrimazole Anti-fungal Cream for 14 days after symptoms disappear to avoid recurrence of the infection.

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

**DO NOT TAKE THE CREAM BY MOUTH. CANESTEN PLUS cream is for external use only.**

***If you use too much (overdose)***

Telephone your doctor or the Poisons Information Centre [0800 POISON (0800 764 766) for advice or go to the nearest Accident and Emergency centre if you think that you or anyone else may have used too much CANESTEN PLUS cream, or may have ingested the cream.

Do this even if there are no signs of discomfort or poisoning. You may need medical attention.

**While you are using CANESTEN PLUS cream**

***Things you must do***

Tell your doctor if you become pregnant, are breastfeeding or intend to breastfeed while using CANESTEN PLUS cream.

In infants, care should be taken not to fasten nappies too tightly over the treated area, as this may increase the chance of side effects.

Tell all doctors, dentists and pharmacists who are treating you that you are using CANESTEN PLUS cream.

***Things you must not do***

**Do not use CANESTEN PLUS cream in or near the eyes.**

**Do not use CANESTEN PLUS cream under dressings or on large areas of the skin unless your doctor tells you to.**

**Do not use large amounts of CANESTEN PLUS cream for a long time.**

If you use large amounts for a long time, the chance of absorption through the skin and the chance of side effects increase.

Ask your doctor or pharmacist if you are concerned about the length of time you have been using CANESTEN PLUS cream.

**Do not give CANESTEN PLUS cream to anyone else, even if they have the same symptoms as yours. Do not use CANESTEN PLUS cream to treat other complaints unless your doctor or pharmacist tells you to.**

***Things to be careful of***

**CANESTEN PLUS cream may reduce the effectiveness and safety of latex products such as condoms and diaphragms if it comes into contact with them.**

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

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CANESTEN PLUS cream is not expected to affect your ability to drive a car or operate machinery.

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## Side Effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well or experience discomfort while you are using CANESTEN PLUS cream.**

CANESTEN PLUS cream helps most people, but a few people may experience unwanted effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

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

- After the application of CANESTEN PLUS cream a slight stinging sensation may occasionally be noticed. This will most likely disappear after several applications.
- Skin reactions (such as hypersensitivity reactions e.g. burning, stinging, swelling or redness) can occasionally occur. Particularly after use on large areas (more than 10% of the body surface) and/or after long term use (longer than 2 - 4 weeks) or under occlusive (air and watertight) dressings, local skin changes may occur.

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

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some patients.

**Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.**

**Ask your doctor or pharmacist if you don't understand anything on this list.**

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## After using CANESTEN PLUS Cream

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### Storage

**Keep your medicine in the original pack until it is time to use it.**

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

**Store CANESTEN PLUS cream below 25°C in a cool, dry place.**

Do not store in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

**Keep CANESTEN PLUS cream where young children cannot reach it.**

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

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### ***Expiry***

The expiry date is marked on the end panel of the carton and is also printed on the crimp at the end of the tube. The date refers to the month and year of expiration e.g. 0812 refers to the eighth month of 2012. The product can be used until the end of this month.

**Do not use after the expiry date printed on the pack.**

### ***Disposal***

If your doctor tells you to stop using CANESTEN PLUS cream or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

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## **Product Description**

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### ***What it looks like***

CANESTEN PLUS cream is a white to slightly yellowish cream, presented in a screw-cap tube containing 30 g of cream.

### ***Ingredients***

CANESTEN PLUS cream contains 10 mg/g (1% w/w) of clotrimazole and 10 mg/g (1% w/w) of hydrocortisone (as 11.2 mg/g hydrocortisone acetate) as active ingredients.

It also contains:

- benzyl alcohol
- cetosteryl alcohol
- tricetareth-4-phosphate
- triglycerides medium-chain
- sodium hydroxide
- water

This medicine does not contain colours or fragrances.

### ***Manufacturer***

CANESTEN PLUS cream is made in Spain.

CANESTEN PLUS cream is marketed by:

Bayer New Zealand Limited  
3 Argus Place  
North Shore 0627  
AUCKLAND  
Toll Free: 0800 847 874

This leaflet was prepared on 16 May 2016.

Ref. Canesten Plus Data Sheet dated 20 November 2012.