

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using CandaDerm®?

CandaDerm® contains the active ingredients clotrimazole and hydrocortisone. CandaDerm® 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, fungal infected nappy rash, ringworm, fungal skin rash and fungal infected eczema or dermatitis.

For more information, see Section [1. Why am I using CandaDerm®?](#) in the full CMI.

### 2. What should I know before I use CandaDerm®?

Do not use if you have ever had an allergic reaction to CandaDerm® or any of the ingredients listed at the end of the CMI.

**Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use CandaDerm®?](#) in the full CMI.

### 3. What if I am taking other medicines?

It is not expected that CandaDerm® will interfere with other medicines you might be using; however, you should always ask your practitioner, doctor or pharmacist if you have any concerns about using CandaDerm® together with other medicines.

See Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use CandaDerm®?

- A small amount of CandaDerm® should be applied thinly and evenly with gentle rubbing to the affected area(s) twice daily until inflammation, itching and redness have subsided and not for more than 7 days (unless directed by a doctor); then use an antifungal-only cream for 14 days after symptoms disappear to avoid recurrence of the infection.

More instructions can be found in Section [4. How do I use CandaDerm®?](#) in the full CMI.

### 5. What should I know while using CandaDerm®?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, pharmacist or dermatologist you visit that you are using CandaDerm®</li><li>• Tell your doctor if you are pregnant, are breast-feeding or intend to breast-feed while using CandaDerm®</li><li>• In babies, take care not to fasten nappies too tightly over the treated area, as this may increase the chance of side effects</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use CandaDerm® in or near the eyes</li><li>• Do not use CandaDerm® under dressings or in large areas on the skin unless your doctor tells you to</li><li>• Do not use large amounts of CandaDerm® for a long time</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Corticosteroid medicine can cause visual disturbance; make sure you know how you react to CandaDerm® or that your vision is clear before driving a car or operating machinery</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store it in a cool dry place below 30 °C and away from moisture, heat or sunlight</li><li>• Discard contents 3 months after opening the tube</li></ul>

For more information, see Section [5. What should I know while using CandaDerm®?](#) in the full CMI.

### 6. Are there any side effects?

Less serious side effects are related to skin reactions: hypersensitivity reactions (slight stinging sensation after application of cream), burning/stinging, swelling, redness.

**Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.**

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# CandaDerm®

Active ingredients: *clotrimazole and hydrocortisone*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using CandaDerm®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CandaDerm®.**

Where to find information in this leaflet:

- [1. Why am I using CandaDerm®?](#)
- [2. What should I know before I use CandaDerm®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use CandaDerm®?](#)
- [5. What should I know while using CandaDerm®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using CandaDerm®?

CandaDerm® contains the active ingredients **clotrimazole and hydrocortisone**. CandaDerm® is a broad spectrum anti-fungal and anti-inflammatory cream.

CandaDerm® 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
- Fungal infected nappy rash
- Ringworm
- Fungal skin rash
- Fungal infected eczema or dermatitis.

### 2. What should I know before I use CandaDerm®?

#### Warnings

**Do not use CandaDerm® if:**

- you are allergic to clotrimazole, hydrocortisone, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- the skin on the area to be treated is cracked or broken
- you have a viral skin infection (such as cold sores, shingles or chicken pox)
- you have other infections of the skin (such as acne, rosacea, perioral dermatitis, lues [syphilis], tuberculosis [which rarely can present as a skin infection, although normally a disease of the lungs])
- you have a reaction of the skin resulting from a vaccination.

**Do not apply CandaDerm® just before having a bath, shower or going swimming.** If you do, you may reduce the effectiveness of the cream.

**Check with your doctor or pharmacist if you:**

- have any other medical conditions
- take any medicines for any other condition
- have cuts or abrasions at or near the area to be treated; the chance of unwanted effects may be increased.

**Do not apply CandaDerm® to large areas (more than 10% of the body surface) or under occlusive (air- and watertight) dressings, such as nappies and bandages.** This may increase systemic absorption.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

**Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.** Your doctor will discuss with you the risks and benefits of using CandaDerm® while you are pregnant.

**Talk to your doctor or pharmacist if you are breast-feeding or intend to breast-feed.** Your doctor will discuss with you the risks and benefits of using CandaDerm® while you are breast-feeding.

**CandaDerm® should not be applied for a long period during pregnancy;** therefore, CandaDerm® should only be used in the first three months of pregnancy after first consulting your doctor.

#### Interactions with latex

- **The ingredients in CandaDerm® cream may affect the latex used in barrier contraceptives such as condoms and diaphragms.** You may need to use other methods of contraception whilst using this medicine and for at least 5 days after last using the cream.

#### Use in children

- **CandaDerm® should only be used on children under 2 years of age (for example, fungal nappy rash) if a doctor has told you to.** Bandages and some nappies that are air- and watertight (occlusive dressings) may increase absorption into the skin. This might be a risk in children, because they have a larger skin surface to body weight ratio than adults.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

It is not expected that CandaDerm® will interfere with other medicines you might be using; however, you should always ask your practitioner, doctor or pharmacist if you have any concerns about using CandaDerm® together with other medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CandaDerm®.**

### 4. How do I use CandaDerm®?

#### How much to use

- Before use, pierce the seal on the tube by inverting the cap over the end of the tube and pressing
- A small amount of CandaDerm® should be applied thinly and evenly with gentle rubbing to the affected area(s)
- Follow the instructions provided by your doctor or pharmacist carefully; these directions may differ from the information contained in this leaflet
- If you do not understand the instructions in this leaflet, ask your pharmacist for help
- DO NOT TAKE THIS CREAM BY MOUTH.

#### When to use CandaDerm®

- CandaDerm® should be applied to the affected area(s) twice daily until inflammation, itching and redness have subsided and not for more than 7 days (unless directed by a doctor); then use an antifungal-only cream for 14 days after symptoms disappear to avoid recurrence of the infection
- Using it more often than you should may not improve your skin problem any faster and may cause or increase side effects.

#### If you use too much CandaDerm®

If you think that you have used too much CandaDerm®, or you have swallowed CandaDerm® cream, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**) (Australia) or the National Poisons Centre (**by calling 0800 POISON [0800 764766]**) (New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### 5. What should I know while using CandaDerm®?

#### Things you should do

- Tell your doctor if you are pregnant, are breast-feeding or intend to breast-feed while using CandaDerm®.
- In babies, take care not to fasten nappies too tightly over the treated area, as this may increase the chance of side effects.

Remind any doctor, dentist, pharmacist or dermatologist you visit that you are using CandaDerm®.

#### Things you should not do

- Do not use CandaDerm® in or near the eyes; if you accidentally get CandaDerm® in your eyes, rinse them well with water
- Do not use CandaDerm® under dressings or in large areas on the skin unless your doctor tells you to
- Do not use large amounts of CandaDerm® for a long time; if you use large amounts for a long time, the chance of absorption through the skin and side effects increase.

#### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how CandaDerm® affects you.**

Corticosteroid medicine can cause visual disturbance. Make sure you know how you react to CandaDerm® or that your vision is clear before driving a car or operating machinery.

#### Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place below 30 °C and away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

#### When to discard your medicine

**Discard contents 3 months after opening the tube.**

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

## Less serious side effects

These can particularly occur:

- after use on large areas (more than 10% of the body surface)
- with long-term use (longer than 2 – 4 weeks)
- under occlusive (air- and watertight) dressings.

Less serious side effects	What to do
<b>Skin reactions:</b> <ul style="list-style-type: none"><li>• hypersensitivity reactions (slight stinging sensation after application of cream)</li><li>• burning/stinging</li><li>• swelling</li><li>• redness</li></ul>	<b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration (Australia) online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) or <https://nzphvc.otago.ac.nz/reporting/> (New Zealand). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

### What CandaDerm® contains

<b>Active ingredients (main ingredients)</b>	Clotrimazole 1% w/w Hydrocortisone 1% w/w
<b>Other ingredients (inactive ingredients)</b>	Cetomacrogol 1000 (cetareth-10) Cetostearyl alcohol Chlorocresol (as preservative) Glycerol Liquid paraffin Propylene glycol Purified water Whit soft paraffin

**Do not take this medicine if you are allergic to any of these ingredients.**

## What CandaDerm® looks like

CandaDerm® is an opaque off-white viscous cream.

CandaDerm® is filled into aluminium tubes with white plastic screw caps each containing 30 g of cream.

AUST R 240672.

## Who distributes CandaDerm®

### In Australia:

AFT Pharmaceuticals Pty Ltd  
113 Wicks Road  
North Ryde  
NSW 2113

Email: [customer.service@aftpharm.com](mailto:customer.service@aftpharm.com)  
Freephone (AU): 1800 AFTPHARM (1800 238 74276)

### In New Zealand:

AFT Pharmaceuticals Ltd  
Level 1, 129 Hurstmere Road  
Takapuna  
Auckland, 0622

Email: [customer.service@aftpharm.com](mailto:customer.service@aftpharm.com)  
Phone: 0800 423 823

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