# TRIMACORTE CREAM

Active ingredient(s): Clotrimazole 1% w/w & Hydrocortisone Acetate 1% w/w

# **Consumer Medicine Information (CMI)**

This leaflet provides important information about using TRIMACORTE Cream. 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 TRIMACORTE Cream.

#### Where to find information in this leaflet:

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

# 1. Why am I using TRIMACORTE?

TRIMACORTE Cream contains the active ingredients Clotrimazole (an antifungal) and Hydrocortisone Acetate (a corticosteroid).

TRIMACORTE Cream is used on the skin to relieve the redness, swelling, itching and discomfort of many inflamed fungal skin problems such as:

- Candidal infections
- Fungal infected dermatitis or eczema
- Fungal skin rash
- External symptoms of thrush
- Tinea infections such as jock itch, ringworm and athlete's foot
- Nappy rash.

Do not use in children under 2 years of age (e.g. nappy rash) unless a doctor has told you to.

For conditions without inflammation, use an antifungal agent without hydrocortisone.

Your doctor or pharmacist may have recommended TRIMACORTE Cream for another purpose. Ask your doctor or pharmacist if you have any questions about why TRIMACORTE Cream has been recommended for you.

TRIMACORTE Cream 30g is only available from your pharmacist.

# 2. What should I know before I use TRIMACORTE?

#### Warnings

Do not use TRIMACORTE Cream if:

- you are allergic to any medicine containing clotrimazole or 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.
- you have skin itching without any inflammation or redness.
- you have acne or rosacea.
- you have a bacterial infection such as school sores.
- you have a viral skin infection (such as cold sores, shingles or chicken pox).
- you have skin which is cracked or broken.
- you have a reaction of the skin resulting from a vaccination.
- You have other serious infections of the skin.

Ask your doctor or pharmacist to be sure you do not have any of these conditions.

**Do not use TRIMACORTE 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.

**Do not use TRIMACORTE Cream just before having a bath, shower or going swimming.** If you do, you may reduce the effectiveness of TRIMACORTE Cream.

If you are not sure whether you should start using TRIMACORTE Cream, contact your doctor or pharmacist.

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

- have or have had any of the conditions listed above or any other medical conditions including receiving a transplanted organ or HIV/AIDS.
- have been or are being treated with medicines, which affect your immune system.
- have a condition associated with a defect in your immune system.
- have a serious illness affecting your immune system.
- are taking any medications containing corticosteroids for asthma or other conditions (e.g. arthritis, organ transplants).
- have allergies to any other medicines or any other substances such as foods, preservatives or dyes.

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 <u>6</u>. 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 the risks and benefits of using TRIMACORTE Cream when pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed. Your doctor will discuss the risks and benefits of using TRIMACORTE Cream when breastfeeding. Do not apply TRIMACORTE Cream to the breasts before breast-feeding.

# 3. What if I am taking other medicines?

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

# Some medicines may interfere with TRIMACORTE Cream and affect how it works.

Tell your doctor or pharmacist if you are using:

- Asthma medication.
- Medication for arthritis.
- Medication for a recent organ transplant you have received.
- Medication for the treatment of HIV/AIDS.

These medicines may affect how well TRIMACORTE Cream works. You may need to use different amounts of your medicine, or you may need to use different medicines. Your doctor or pharmacist will advise you.

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

# 4. How do I use TRIMACORTE?

#### How much to use

- TRIMACORTE Cream is for external use only.
- Gently rub a small amount of TRIMACORTE Cream into the affected area and surrounding skin twice daily.
   Apply enough cream to disappear into the skin without leaving any on the skin.
- Do not use tight fitting nappies or plastic pants on a child being treated in the area of the nappy, as this may increase the chance of side effects. If the location of the skin condition is in an area normally covered with clothing, you should ensure that loose clothing is worn over the area being treated.
- Follow all directions given to you by your doctor or pharmacist and the instructions provided with the medicine. If you do not understand the instructions on the box, tube or this leaflet, ask your doctor or pharmacist for help.
- It is important to use TRIMACORTE 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 is more often than you should may not improve your skin problems any faster and may cause or increase side effects.
- Do not exceed the recommended dosage.

#### When to use TRIMACORTE

- TRIMACORTE Cream should be applied twice daily at about the same time.
- You should use TRIMACORTE Cream only until the inflammation has subsided, and not for more than 7 days unless your doctor or pharmacist tells you to. If you use TRIMACORTE Cream for longer than your doctor or pharmacist tells you to the chance of side effects may increase. You should apply a cream containing only an anti-fungal agent for an extra two weeks after the inflammation has subsided. You must do this otherwise there might be a chance of the condition returning.

If you are not sure of how long you need to use TRIMACORTE Cream, talk to your doctor or pharmacist.

If you forgot to use it and it is almost time for your next application of TRIMACORTE Cream, skip the application you missed and apply the cream when you are next meant to. Otherwise, use it as soon as you remember, and then go back to using your cream as you would normally.

Do not use a double dose to make up for the dose that you missed.

#### If you use too much TRIMACORTE

If you think that you have used too much TRIMACORTE Cream or if you think that you or someone else may have swallowed TRIMACORTE Cream, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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. You may need urgent medical attention.

# 5. What should I know while using TRIMACORTE?

#### Things you should do

- If you feel that TRIMACORTE Cream is not helping your condition, tell your doctor or pharmacist
- Tell your doctor or pharmacist if, for any reason, you have not used TRIMACORTE Cream exactly as prescribed. Otherwise, your doctor or pharmacist may think that it was not effective and change your treatment unnecessarily.
- If you become pregnant while using TRIMACORTE Cream, tell your doctor or pharmacist.

Remind any doctor or pharmacist you visit that you are using TRIMACORTE Cream.

#### Things you should not do

 Do not apply under dressings or on large areas of skin unless your doctor tells you.

- Do not apply in or near the eyes.
- Do not use to treat other complaints unless your doctor or pharmacist tells you to.
- Do not use to treat acne.
- Do not use on children under 2 years of age unless a doctor has told you to.
- Do not use for more than 7 days unless a doctor has told you.
- Do not use TRIMACORTE Cream on skin areas that rub together such as under the arm or in the groin area unless your doctor or pharmacist tells you to.
- Do not wear tight fitting clothing over the area being treated with TRIMACORTE Cream.
- Do not give TRIMACORTE Cream to anyone else, even if they have the same symptoms as yours.

Do not use large amounts of TRIMACORTE 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 may increase. Ask your doctor or pharmacist if you are concerned about the length of time you have been using TRIMACORTE Cream.

## **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how TRIMACORTE affects you. It is not expected that TRIMACORTE Cream will affect these activities.

## **Drinking alcohol**

Tell your doctor or pharmacist if you drink alcohol.

Alcohol is not expected to impact on the use of TRIMACORTE Cream.

#### Looking after your medicine

- Keep TRIMACORTE Cream in a cool dry place where the temperature stays below 25°C.
- Do not refrigerate or freeze.

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

Store it in a cool dry place 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.

#### 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/common side effects

Less serious side effects	What to do
<ul> <li>Drying, cracking, blistering, peeling, thinning, tightening or redness of the skin</li> <li>Burning or stinging feeling on the skin</li> <li>Bruising of the skin</li> <li>Acne-type lumps on the skin</li> <li>Itching or irritation of skin &amp; loss of skin colour</li> <li>Skin condition getting worse</li> <li>Other obvious unexpected changes to the skin being treated</li> <li>Blurred vision</li> </ul>	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

## Serious/rare side effects

Serious side effects	What to do
<ul> <li>Skin condition gets rapidly worse or skin becomes swollen</li> <li>Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting</li> </ul>	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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 online at <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. 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 TRIMACORTE contains

Active ingredients (main ingredient)	Clotrimazole 1% w/w Hydrocortisone acetate 1% w/w
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Other ingredients	Cetostearyl alcohol
(inactive ingredients)	Ceteareth-20
	Light liquid paraffin
	Propylene glycol
	Water
Potential allergens	n/a

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

TRIMACORTE Cream does not contain lanolin, paraben preservatives or fragrances and washes off with water.

## What TRIMACORTE looks like

TRIMACORTE Cream is a smooth, non-greasy white cream, which is available in a 30 gram tube in a carton (AUST R 291705).

# Who distributes TRIMACORTE Cream

Nova Pharmaceuticals Australasia Pty Ltd Suite 305, 10 Norbrik Drive Bella Vista NSW 2153

## **Sponsor**

Nova Pharmaceuticals Australasia Pty Ltd Suite 305, 10 Norbrik Drive Bella Vista NSW 2153

This leaflet was prepared in July 2022.