

# Metronidazole Gel

Metronidazole 0.5% w/w

---

## Consumer Medicine Information

---

### What is in this leaflet?

---

Please read this leaflet carefully before you start using Metronidazole Gel.

This leaflet answers some common questions about Metronidazole Gel. 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 doctor has weighed the risks of you using Metronidazole Gel against the benefits they expect it will have for you.

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

Keep this leaflet with your tube. You may wish to read it again later.

---

### What is Metronidazole Gel used for?

---

Metronidazole Gel is used for the treatment of inflammatory papules and pustules of rosacea. Skin affected by rosacea has one or more of the following features: a redness that looks like a blush; pimples; small knobbly lumps on the nose and/or thin red lines due to enlarged blood vessels.

Your doctor may have prescribed Metronidazole Gel for another use. Ask your doctor if you have any questions about why

Metronidazole Gel has been prescribed for you.

The active ingredient in Metronidazole Gel is metronidazole, which belongs to the class of medicines known as antiprotozoals and antibacterials.

It is not clear how Metronidazole Gel works however it is known to have antibacterial and anti-inflammatory properties.

In many cases medications may take several weeks to show an effect. They may have to be used regularly to keep the rosacea under control.

This medicine is only available with a doctor's prescription.

---

### Before you use Metronidazole Gel

---

#### **Do not use if:**

You must not use Metronidazole Gel if you have an allergy to:

- Metronidazole
- Any of the ingredients listed at the end of this leaflet (See "Ingredients")

Metronidazole Gel is not recommended for children as there is not enough information on its use in that age group.

#### **Tell your doctor if:**

You must tell your doctor if:

- You have had an allergic reaction to any of the ingredients listed in the section labelled "Ingredients".

- You are pregnant or intend to become pregnant. There are no well controlled studies of the therapy of Metronidazole Gel in pregnant women. *Your doctor will discuss with you the possible risks and benefits of using Metronidazole Gel during pregnancy.*
- You are breast feeding, or wish to breastfeed. It is recommended that you do not breastfeed while using Metronidazole Gel. *Your doctor will discuss with you the possible risks and benefits of using Metronidazole Gel during breastfeeding.*
- You have had or currently have a blood disorder.

#### **Taking other medicines:**

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

In particular, tell your doctor if you are taking any medicines used to prevent clotting of the blood.

*Some medicines may affect the way other medicines work. They may also react with Metronidazole Gel resulting in unwanted side effects. Your doctor or pharmacist will be able to tell you which medicines are safe to take while using Metronidazole Gel.*

In future, before you start to take any other medicines, tell your doctor or pharmacist that

you are using Metronidazole Gel.

---

## How do I use Metronidazole Gel?

---

### **Things you must do:**

*Metronidazole Gel is only for use on the skin.*

Follow your doctor's instructions about how to use Metronidazole Gel. Read the directions label of your Metronidazole Gel carefully. If you have any concerns about how to use Metronidazole Gel, talk to your doctor or pharmacist.

Wash and dry your hands before applying the gel.

Metronidazole Gel can be applied once or twice daily, depending on your condition. Your doctor will tell you how often to use Metronidazole Gel.

Squeeze a small quantity of Metronidazole Gel onto your finger tips and rub a thin film onto the affected areas. The affected area should be cleaned before applying Metronidazole Gel. This will lessen the possibility of irritation.

Use a sunscreen when exposure to the sun cannot be avoided.

*Keep using your Metronidazole Gel for as long as your doctor tells you.*

Continue to use Metronidazole Gel even though there may not be an immediate effect. Medicines can take several weeks to show an effect.

### **If you forget to apply:**

If you forget to apply Metronidazole Gel, use it again as directed, as soon as you remember.

Do not try and apply twice the amount of gel at one time. This may increase the chance of

you getting an unwanted side effect.

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

---

## What do I do if I swallow it?

---

Metronidazole Gel is intended for external use only.

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have swallowed Metronidazole Gel. Do this, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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

Keep telephone numbers for these places handy.

---

## While you are using Metronidazole Gel

---

### **Things you must do:**

*Tell your doctor if, for any reason, you have not used your gel exactly as directed.*

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

*Tell any other doctors, dentists, and pharmacists who are treating you that you are using Metronidazole Gel.*

If you are about to be started on any new medicines, remind you doctor, dentist or pharmacist that you are using Metronidazole Gel.

*Tell your doctor immediately if you become pregnant while using Metronidazole Gel.*

### **Things you must not do:**

*Be careful not to use cosmetic products containing alcohol, abrasives or medicated soaps. They may cause an extra irritant or drying effect.*

**Do not give this gel to anyone else, even if his or her symptoms seem similar to yours.**

**Do not use Metronidazole Gel to treat any other skin problems unless your doctor says to.**

### **Things you can do:**

Make-up can be used after applying the Gel.

A moisturiser can also be used if the skin is dry.

### **Things to be careful of:**

Metronidazole Gel should not come into contact with eyes. Contact with the eye can cause irritation. If accidental contact occurs, rinse thoroughly with water and pat dry.

Avoid conditions known to make rosacea worse, such as hot, spicy foods, alcohol, extremes of temperature and excessive exposure to sunlight.

---

## What are the side effects?

---

Like other medicines, Metronidazole Gel can sometimes cause unwanted 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. If you get any unwanted side effects, tell your doctor or pharmacist.

**Tell your doctor if you experience any of the following and they worry you:**

- Redness and mild dryness

- Itching or burning
- Irritation and stinging
- Aggravated rosacea or acne
- Watering or tearing of the eye
- Conjunctivitis

These side effects can occur with Metronidazole Gel. They are not very common and are usually mild.

Use Metronidazole Gel less frequently if your face becomes hot, red, itchy or swollen.

If a serious reaction occurs, or if a reaction persists, discontinue use of Metronidazole Gel and consult your doctor.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

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

---

## How do I store Metronidazole Gel?

---

### **Storage:**

**Metronidazole Gel should be stored in a safe place where children cannot reach it.**

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

Keep your Metronidazole Gel in its tube until it is time to use it.

Metronidazole Gel should be stored below 25°C.

Do not leave Metronidazole Gel in the car or on windowsills. Do not store medicines in the bathroom or near a sink. Heat and dampness can destroy some medicines.

### **Disposal:**

If your doctor tells you to stop using Metronidazole Gel, ask your pharmacist what to do with any gel that is left over.

---

## Product Description

---

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

A 5mg per g clear and colourless gel. It comes in 10g tubes and is available by prescription only.

### **Ingredients:**

#### *Active Ingredients:*

Metronidazole 5 mg/ g

#### *Inactive Ingredients:*

- Sodium phosphate dibasic - anhydrous
- Citric acid anhydrous
- Propylene glycol
- Hydroxyethylcellulose
- Purified Water

---

## Where to go for further information

---

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. Should you have any further questions regarding this product, please contact your doctor or pharmacist.

---

## Sponsor

---

Metronidazole Gel is supplied in Australia by:

ORION Laboratories Pty Ltd  
25-29 Delawney Street  
Balcatta WA 6021

*Australian Registration Number:* AUST R 10846

This leaflet was prepared in January 2004

*Date of last amendment:*  
14 June 2006

*Code:* MET001523F\_2\_CMI