

# ROZEX<sup>®</sup> GEL

## 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 Rozex gel?

ROZEX GEL contains the active ingredient metronidazole. ROZEX GEL is used to treat the inflammatory papules and pustules of rosacea.

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

### 2. What should I know before I use ROZEX GEL?

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

**Talk to your doctor if you have any other medical conditions including Cockayne Syndrome, 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 ROZEX GEL?](#) in the full CMI.

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

Some medicines may interfere with ROZEX GEL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use ROZEX GEL?

- Apply morning and evening to clean dry skin.

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

### 5. What should I know while using ROZEX GEL?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using ROZEX GEL.</li><li>• Tell your doctor or nurse if ROZEX GEL is not helping your condition.</li><li>• Tell your doctor if you become pregnant while using ROZEX GEL.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use cosmetic products that contain alcohol or are abrasive.</li><li>• Do not use medicated soaps.</li><li>• Avoid or minimise sunlight or other sources of UV light exposure.</li><li>• Unnecessary or prolonged use of ROZEX GEL should be avoided.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• The effects of this medicine on a person's ability to drive and use machines has not been assessed.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• <b>Avoid drinking alcohol while using ROZEX GEL</b></li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep the medicine in a cool dry place where the temperature stays below 25°C.</li><li>• Do not store it in the bathroom, near a sink, on a window sill, or in a car.</li></ul>

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

### 6. Are there any side effects?

Dry skin, reddening of the skin, severe itching, skin discomfort, skin irritation, worsening of rosacea, hyperpigmentation and other pigmentation disorders, contact dermatitis, reduced sense of touch or sensation, tingling or pricking sensation (pins and needles), numbness in the extremities, metallic taste, seborrhoea (red, itchy rash and white scales), sunburn, skin infection, hives, gastritis, bronchitis, stuffy runny nose, skin exfoliation, swelling face, nausea, excess watery fluid collection on the face or eyelids, hypothyroidism, Bursitis (inflammation or irritation of the bursa), Myalgia (muscle pain), osteoporosis, conjunctivitis, abscesses.

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.

# ROZEX® GEL

Active ingredient: *metronidazole*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ROZEX GEL. **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 ROZEX GEL.**

Where to find information in this leaflet:

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

## 1. Why am I using ROZEX GEL?

ROZEX GEL contains the active ingredient **metronidazole**. ROZEX GEL is an antiprotozoal and antibacterial medicine.

ROZEX GEL is used for the treatment of inflammatory papules and pustules of rosacea.

## 2. What should I know before I use ROZEX GEL?

### Warnings

**Do not use ROZEX GEL if:**

- You are allergic to metronidazole, 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 Cockayne Syndrome.
- You are pregnant.

**Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition
- are breastfeeding
- are planning to become pregnant

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 if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

With not enough information available on the effect of ROZEX GEL on pregnant women, ROZEX GEL is not recommended during pregnancy.

## 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.

Oral metronidazole has been shown to boost the effect of warfarin and other coumarin anticoagulants. It is unknown how ROZEX GEL may interact with these products.

**Some medicines may interfere with ROZEX GEL and affect how it works.**

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

## 4. How do I use ROZEX GEL?

### How much to use

- Wash and dry your hands before applying the gel.
- Squeeze a small quantity of ROZEX GEL on to your fingertips and rub a thin film onto the affected areas.
- Avoid getting ROZEX GEL in your eyes.
- Use a sunscreen when exposure to the sun cannot be avoided.
- ROZEX GEL is only for use on the skin.
- Follow the instructions provided and use ROZEX GEL until your doctor tells you to stop.

### When to use ROZEX GEL

- ROZEX GEL should be used morning and evening on a clean dry face.
- Continue to use it even though there may not be an immediate effect. Medicines can take several weeks to show an effect. The average period of treatment is usually three to four months. The recommended duration should not be exceeded.

### If you forget to use ROZEX GEL

ROZEX GEL should be used regularly at the same times each day. If you miss your dose at the usual time, use it again as directed, as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and apply your next dose when you are meant to.

Do not apply a double dose to make up for forgotten individual doses.

- If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

### If you use too much ROZEX GEL

If you think that you have used too much ROZEX GEL, 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.

## 5. What should I know while using ROZEX GEL?

### Things you should do

Call your doctor straight away if you:

- Think you have an allergy.
- Symptoms of an allergic reaction may include:
  - swelling of the face, lips, tongue, or other parts of the body
  - rash, itching, or hives of the skin, especially on the areas where the gel was applied.
- if the condition worsens / does not improve, go to the emergency department at your nearest hospital.

Remind any doctor, dentist or pharmacist you visit that you are using ROZEX GEL.

### Things you should not do

- Avoid ROZEX GEL coming into contact with eyes or mucous membranes. If accidental contact occurs, rinse thoroughly with water and pat dry.
- Do not use cosmetic products that contain alcohol or are abrasive.
- Do not use medicated soaps. These may have an extra drying or irritant effect.
- Unnecessary or prolonged use of ROZEX GEL should be avoided as the long-term safety is unknown.
- Do not use ROZEX GEL after the expiry date (EXP) printed on the pack has passed, or if the packaging is torn or shows signs of tampering.
- If it has expired or is damaged, return it to your pharmacist for disposal.

### Driving or using machines

Be careful before you drive or use any machines or tools until you know how ROZEX GEL affects you.

### Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol has been shown to interact with metronidazole when taken orally.

### Looking after your medicine

- Keep the medicine in a cool dry place where the temperature stays below 25°C.

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.

### When to discard your medicine

### 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.

## 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 about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• Dry skin</li><li>• Superficial reddening of the skin</li><li>• Severe itching of the skin</li><li>• Skin discomfort (burning, dryness, pain of skin/stinging)</li><li>• Skin irritation</li><li>• Worsening of rosacea</li><li>• Hyperpigmentation and other pigmentation disorders</li><li>• Contact dermatitis</li><li>• Reduced sense of touch or sensation</li><li>• Tingling or pricking sensation ('pins and needles')</li><li>• Numbness in the extremities</li><li>• Dysgeusia (metallic taste)</li><li>• Seborrhoea (red, itchy rash and white scales)</li><li>• Sunburn</li><li>• Skin infection</li><li>• Hives</li><li>• Gastritis</li><li>• Bronchitis</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<ul style="list-style-type: none"> <li>• Stuffy runny nose</li> <li>• Skin exfoliation</li> <li>• Swelling face</li> <li>• Nausea</li> <li>• Excess watery fluid collection on the face or eyelids</li> </ul>	
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### Rare side effects

Rare side effects	What to do
<ul style="list-style-type: none"> <li>• Hypothyroidism</li> <li>• Bursitis (inflammation or irritation of the bursa)</li> <li>• Myalgia (muscle pain)</li> <li>• Osteoporosis</li> <li>• Conjunctivitis</li> <li>• Abscess</li> </ul>	<p><b>Speak to your doctor, if you notice any of these rare side effects.</b></p>

**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 [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What ROZEX GEL contains

<b>Active ingredient (main ingredient)</b>	7.5 mg per gram metronidazole
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>- Methyl hydroxybenzoate,</li> <li>- Propyl hydroxybenzoate,</li> <li>- Disodium edetate,</li> <li>- Carbomer 940,</li> <li>- Propylene glycol,</li> <li>- Sodium hydroxide to adjust pH,</li> <li>- Purified water q.s. to 1.0g.</li> </ul>

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

### What ROZEX GEL looks like

ROZEX GEL is a homogeneous gel in an aluminium tube with a screw cap containing 2g, 5g, 15g, 30g, and 50g of gel.

Not all pack sizes may be available.

(AUST R 15211).

### Who distributes ROZEX GEL

Galderma Australia Pty Ltd

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North Sydney, NSW 2060

Telephone 1800 800 765

Distributed in New Zealand by:

Healthcare Logistics'

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Made in France

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