

# RejuveNail® Anti-fungal Nail Lacquer

## 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 RejuveNail Anti-fungal Nail Lacquer?

RejuveNail contains the active ingredient ciclopirox. RejuveNail Anti-fungal Nail Lacquer is used to treat mild to moderate fungal nail infections that does not involve the lunula, by painting it onto the infected fingernails or toenails. The lunula is the crescent-shaped area (white half-moon) at the base of the nail. For more information, see Section [1. Why am I using RejuveNail Anti-fungal Nail Lacquer?](#) in the full CMI.

### 2. What should I know before I use RejuveNail Anti-fungal Nail Lacquer?

Do not use if you have ever had an allergic reaction to RejuveNail Anti-fungal Nail Lacquer 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 RejuveNail Anti-fungal Nail Lacquer?](#) in the full CMI.

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

Some medicines may interfere with RejuveNail Anti-fungal Nail Lacquer 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 RejuveNail Anti-fungal Nail Lacquer?

- Before starting treatment, clip the free edges of the infected nails. Before applying RejuveNail Anti-fungal Nail Lacquer, wash and dry the infected nails
- Apply in a thin layer over the entire infected nail surface and 5mm of surrounding skin and if possible under the free edge of the nail. Allow to dry for approximately 30 seconds
- The treated nail should not be washed for at least 6 hours, therefore, application in the evening before going to bed is recommended. Normal hygiene practices can be followed after 6 hours. Regular (weekly) clipping of the infected nails is recommended throughout treatment with RejuveNail Anti-fungal Nail Lacquer.

More instructions can be found in Section [4. How do I use RejuveNail Anti-fungal Nail Lacquer?](#) in the full CMI.

### 5. What should I know while using RejuveNail Anti-fungal Nail Lacquer?

|                             |                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Things you should do        | <ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using RejuveNail Anti-fungal Nail Lacquer.</li></ul>                                                                                                                                                                                                                                                                           |
| Things you should not do    | <ul style="list-style-type: none"><li>• Do not use RejuveNail Anti-fungal Nail Lacquer if you are allergic to ciclopirox, or any of the ingredients listed at the end of this leaflet.</li><li>• Do not use RejuveNail Anti-fungal Nail Lacquer in children or adolescents below 18 years of age.</li></ul>                                                                                                                            |
| Looking after your medicine | <ul style="list-style-type: none"><li>• Keep your nail lacquer bottle in the carton to protect it from exposure to light.</li><li>• Ensure that the bottle cap has been tightly closed after each use in order to prevent the lacquer from drying.</li><li>• Store the bottle in a cool dry place below 30°C. Do not refrigerate.</li><li>• Keep away from open flames and sources of ignition as this product is flammable.</li></ul> |

For more information, see Section [5. What should I know while using RejuveNail Anti-fungal Nail Lacquer?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include redness, scaling, burning, or itching on and around the application area. These are mild side effects of this medicine and are usually short-lived. 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.

# RejuveNail® Anti-fungal Nail Lacquer

Active ingredient(s): *Ciclopirox* 8% w/w

## Consumer Medicine Information (CMI)

This leaflet provides important information about using RejuveNail Anti-fungal Nail Lacquer. **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 RejuveNail Anti-fungal Nail Lacquer.**

Where to find information in this leaflet:

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

## 1. Why am I using RejuveNail Anti-fungal Nail Lacquer?

RejuveNail Anti-fungal Nail Lacquer contains the active ingredient *ciclopirox*. It is used to treat mild to moderate fungal nail infections that does not involve the lunula, by painting it onto the infected fingernails or toenails. The lunula is the crescent-shaped area (white half-moon) at the base of the nail.

A fungal infection usually causes discolouring, thickening and crumbling nails. It is an unsightly and potentially painful problem that does not resolve without treatment.

RejuveNail Anti-fungal is not suitable for use in severe infections where the lunula is affected. In this case you should talk to your health care practitioner.

The active ingredient, *ciclopirox*, belongs to a family of medicines called anti-fungals. It works by preventing the growth of fungi and killing a wide variety of fungi that cause nail infections.

Fungal nail infections are hard to treat and full cure depends on several factors, including how badly damaged the nail is. While RejuveNail Anti-fungal Nail Lacquer can cure the fungal infection it cannot repair the damage, and so a full cure can be expected in less than one in three people.

## 2. What should I know before I use RejuveNail Anti-fungal Nail Lacquer?

### Warnings

**Do not use RejuveNail Anti-fungal Nail Lacquer if:**

- you are allergic to *ciclopirox*, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

**Do not use RejuveNail Anti-fungal Nail Lacquer in children or adolescents below 18 years of age.**

- Safety and effectiveness in this age group has not been established.

**Do not use RejuveNail Anti-fungal Nail Lacquer after the expiry date (EXP) printed on the pack 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.

**Do not use the bottle if it has been more than 6 months from the time you first opened the bottle.**

- Discard 6 months after first opening the bottle.

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

- are allergic to any other medicines, foods, dyes or preservatives
- have any of the following medical conditions:
  - fungal nail infections involving the lunula
  - painful or seriously damaged nails, skin conditions such as psoriasis or any other chronic skin condition.
  - diabetes or problems clipping the nail
  - you have any other health problems
- take any medicines for any other condition

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 or pharmacist will discuss the possible risks and benefits of using RejuveNail Anti-fungal Nail Lacquer during pregnancy.

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

Your doctor or pharmacist will discuss the possible risks and benefits of using RejuveNail Anti-fungal Nail Lacquer when breastfeeding.

## 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RejuveNail Anti-fungal Nail Lacquer.

#### 4. How do I use RejuveNail Anti-fungal Nail Lacquer?

Record the date of first opening on the carton in the allocated position, so that you know how long you should keep the medicine. The bottle should be discarded 6 months after first use.

Before starting treatment, clip the free edges of the infected nails. If you have diabetes or problems clipping the nail, you may consult a podiatrist.

##### How to apply the nail lacquer?

###### ADULTS (18 years and over):

- Before applying RejuveNail Anti-fungal Nail Lacquer, wash and dry the infected nails
- Apply in a thin layer over the entire infected nail surface and 5mm of surrounding skin and if possible under the free edge of the nail
- Allow to dry for approximately 30 seconds
- The treated nail should not be washed for at least 6 hours, therefore, application in the evening before going to bed is recommended. Normal hygiene practices can be followed after 6 hours.
- Regular (weekly) clipping of the infected nails is recommended throughout treatment with RejuveNail Anti-fungal Nail Lacquer.

RejuveNail Anti-fungal Nail Lacquer does not need to be removed with a solvent or by nail filing as it washes off with water. In case of unintentional removal by washing within 6 hours of application, it can be reapplied to the nail. Cosmetic nail polish or similar products are not recommended during treatment.

**To prevent the solution from evaporating and drying up, screw the cap firmly immediately after use.**

##### How often to apply the nail lacquer?

Apply RejuveNail Anti-fungal Nail Lacquer on the infected nails once daily or as otherwise directed by your doctor or pharmacist.

It should be left on the nail for at least 6 hours. In case of unintentional removal by washing, it can be reapplied.

##### If you forget to apply it

**Use it as soon as you remember, then go back to using the nail lacquer as you would normally. Do not use a double dose to make up for the missed dose.**

This may increase your chances of an unwanted side effect.

#### How long should RejuveNail Anti-fungal Nail Lacquer be used for?

For best results, RejuveNail Anti-fungal Nail Lacquer should be used every day for at least 6 to 12 months. The infected nail should be trimmed at weekly intervals.

Treatment should be continued until the infection has cleared and healthy nails have regrown. This usually takes about 6 months for fingernails and about 9 to 12 months for toenails.

Nails only grow about 2mm per month so don't be discouraged if there is no visible improvement after a few weeks.

If you stop the treatment before your nails are clear, the fungi may not have been destroyed and the condition could get worse again.

You should see your doctor if your symptoms worsen or do not improve after 6 months for fingernails and 9-12 months for toenails as oral medication may be required.

##### In case of accidental swallowing

###### 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 if you think that you or anyone else may have swallowed RejuveNail Anti-fungal Nail Lacquer, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

#### 5. What should I know while using RejuveNail Anti-fungal Nail Lacquer?

##### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using RejuveNail Anti-fungal Nail Lacquer.
- If you become pregnant while you are using this medicine, stop using it and tell your doctor or pharmacist.
- If you plan to have surgery that requires a general anaesthetic, tell your doctor or dentist that you are using this medicine.

##### Things you should not do

- **RejuveNail Anti-fungal Nail Lacquer is for external use only. It must not be used on open wounds or injuries, or on skin that has a rash or infection.**
- **Avoid getting it into your eyes.**
- Your eyes may become irritated if you touch them after applying RejuveNail Anti-fungal Nail Lacquer to your fingernails. If this happens, rinse your eyes with clean water and tell your pharmacist or doctor if irritation persists.
- **Do not use a nail file on healthy nails if you have used it on infected nails.**

- Do not use artificial nails during treatment with RejuveNail Anti-fungal Nail Lacquer.
- Do not apply cosmetic nail polish or other nail medication on the nails being treated.
- Do not give RejuveNail Anti-fungal Nail Lacquer to anyone else to use, even if they have the same condition as you.
- Do not use RejuveNail Anti-fungal Nail Lacquer to treat any other complaints unless your doctor or pharmacist tells you to.

### Looking after your medicine

- Keep your nail lacquer bottle in the carton to protect it from exposure to light.
- Discard the bottle 6 months after first opening.
- On first opening of the product, record the date of first opening on the carton in the allocated position, so that you know how long you should keep the medicine.
- Ensure that the bottle cap has been tightly closed after each use in order to prevent the lacquer from drying.
- Store the bottle in a cool dry place below 30°C. Do not refrigerate.
- At temperatures below 15°C the nail lacquer may gel. To reverse, warm to room temperature (25°C) by rubbing the bottle between your hands until the solution is clear.
- This has no impact on the product quality or effectiveness.
- Do not store the bottle or any other medicine, in the bathroom or near a sink. Do not leave it in the car or on windowsills.
- Heat and dampness can destroy some medicines.
- Keep it where children cannot reach it.
- A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.
- Keep away from open flames and sources of ignition as this product is flammable.

### 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. RejuveNail Anti-fungal Nail Lacquer is generally very well tolerated but it may have unwanted side effects in a few people.

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

| Less serious side effects                                                                                                                                                                                                                                                                                                                                                                                                                                 | What to do                                                                                                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• redness, scaling, burning, or itching on and around the application area</li> <li>• rash</li> <li>• eczema (dry, red, itchy skin)</li> <li>• allergic dermatitis (inflammation of the skin)</li> <li>• transient discolouration of the nail - this reaction can also be attributed to the fungal nail disease itself</li> </ul> <p>These are mild side effects of this medicine and are usually short-lived.</p> | <p><b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</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.

## 7. Product details

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

### What RejuveNail Anti-fungal Nail Lacquer contains

|                                          |                                                                                                                                                                                 |
|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Active ingredient (main ingredient)      | Ciclopirox 80 mg/g                                                                                                                                                              |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> <li>• Ethyl acetate</li> <li>• Ethanol</li> <li>• Cetostearyl alcohol</li> <li>• Hydroxypropyl chitosan</li> <li>• Purified water</li> </ul> |
| Potential allergens                      | None                                                                                                                                                                            |

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

### What RejuveNail Anti-fungal Nail Lacquer looks like

RejuveNail Anti-fungal Nail Lacquer is a clear, colourless to slightly yellow liquid.

RejuveNail Anti-fungal Nail Lacquer is supplied in a pack containing either 3.3mL or 6.6mL in a clear glass bottle with a screw cap fitted with an applicator brush.

Not all presentations may be marketed.

### **Who distributes RejuveNail Anti-fungal Nail Lacquer**

RejuveNail Anti-fungal Nail Lacquer is supplied in Australia by:

A. Menarini Australia Pty Ltd

Sydney, Australia

Customer Information: 1800 644 542

[www.rejuvenail.com.au](http://www.rejuvenail.com.au)

AUST R 197723

RejuveNail Anti-fungal Nail Lacquer is supplied in New Zealand by:

A. Menarini New Zealand Pty Ltd

4 Whetu Place, Rosedale 0632 Auckland

Customer Information: 0800 102 349

[www.rejuvenail.co.nz](http://www.rejuvenail.co.nz)

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[vA05-0]