

RejuveNail[®] Anti-fungal Nail Lacquer

Ciclopirox 8% w/w

Consumer Medicine Information

What is in this leaflet

This leaflet provides important information about RejuveNail Anti-fungal Nail Lacquer. Please read it carefully before you start using it.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. If you have any concerns about using this medicine or are not sure about how to use your medicine, ask your pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What REJUVENAIL ANTI-FUNGAL NAIL LACQUER is used for

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.

Before you use REJUVENAIL ANTI-FUNGAL NAIL LACQUER

When you must not use it

Do not use RejuveNail Anti-fungal Nail Lacquer if:

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

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.

Before you start to use it

Check with your doctor or pharmacist if you are allergic to any other medicines, foods, dyes or preservatives.

Check with your doctor or pharmacist if you 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

Tell 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.

Tell 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.

Taking other medicines

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

Your doctor or pharmacist have more information on medicines to be careful with or avoid while using RejuveNail Anti-fungal Nail Lacquer.

How to 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

Immediately telephone your doctor or Poisons Information Centre (Australia telephone 13 11 26, New Zealand telephone 0800 764 766), or go to Accident and Emergency at your nearest hospital, 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.

While you are using REJUVENAIL ANTI-FUNGAL NAIL LACQUER

Things you must do

Tell your doctor or pharmacist that you are using RejuveNail Anti-fungal Nail Lacquer if you are about to be started on a new medicine.

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 must 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.

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.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- skin irritation, redness, scaling, burning, itching or rash on and around the application area
- discolouration of the nail
- allergic dermatitis (inflammation of the skin)

These are mild side effects of this medicine and are usually short-lived.

Talk to your doctor or pharmacist if you notice anything else that is making you feel unwell.

After using it

Storage

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.

Product description

What it 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 6.6mL in a clear glass bottle with a screw cap fitted with an applicator brush.

Ingredients

Active ingredient:

- Ciclopirox 80 mg/g

Inactive ingredients:

- Ethyl acetate
- Ethanol
- Cetostearyl alcohol
- Hydroxypropyl chitosan
- Purified water

Supplier

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

A. Menarini Australia Pty Ltd
Level 8, 67 Albert Ave,
Chatswood NSW 2067

Customer Information: 1800 644 542
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

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