

RejuveNail[®] Anti-fungal Nail Lacquer

Ciclopirox 8% w/w

Consumer Medicine Information (CMI)

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 painted onto the fingernails or toenails to treat fungal infections.

Ciclopirox belongs to a family of medicines called anti-fungals. These medicines work by 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 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. 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 lunula is the crescent-shaped area at the base of the nail.

The active substance, ciclopirox, prevents the growth of fungi and destroys them, improving the appearance of your nails.

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
- the package is torn or shows signs of tampering
- the expiry date (EXP) printed on the carton has passed
- it is more than 6 months from the time you first used the bottle

Use in children.

Do not use in children or adolescents below 18 years of age as there is

insufficient experience in this age group.

Before you start to use it

Tell your doctor or pharmacist if:

- you are allergic to any other medicines, foods, dyes or preservatives
- you have any other health problems
- you are taking any other medicines
- 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
- 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

On first use of the product, record the date of first use 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.

How to use REJUVENAIL® ANTI- FUNGAL NAIL LACQUER

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 nail should not be washed for at least 6 hours, therefore, application in the evening before going to bed is recommended. After that time, normal hygienic practices can be followed

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

It 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, it can be reapplied. It is recommended to remove as much as possible of the infected nail by clipping the nails. It is not recommended to use cosmetic nail polish or other nail cosmetic products on the treated nails.

How often to apply RejuveNail® Anti-fungal nail lacquer

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

In case of unintentional removal by washing, it can be reapplied.

If you forget to paint on the RejuveNail® Anti-fungal nail lacquer, use it as soon as you remember. Then go back to using the lacquer as you

would normally. Do not use a double dose to make up for the missed dose as it may increase your chances of an unwanted side effect.

How long should RejuveNail® Anti-fungal nail lacquer be used

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

Treatment should be continued until the infected nails are clear 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 treatment before your nails are clear, the fungi may not have disappeared 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 12 months for toenails as oral medication may be required.

In case of accidental swallowing

Immediately telephone your doctor or Poisons Information Centre (131 126), 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.

How to use 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

Do not put it on open wounds or injuries, or on skin that has a rash or infection.

BE CAREFUL NOT TO GET IT IN 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 or rash around the application area
- change in shape or colour of the nail
- ingrown toenail
- tenderness, bleeding or burning of the nail bed
- increased pain beneath the nail
- 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 use.

On first use of the product, record the date of first use on the carton in the allocated position, so that you know how long you should keep the medicine.

Store the bottle in a cool dry place below 30°C.

Heat and dampness can destroy some medicines.

Do not refrigerate.

Do not store it or any other medicine, in the bathroom or near a sink.

Do not leave it in the car or on windowsills.

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.

At temperatures below 15°C the nail lacquer may gel. To reverse, warm to room temperature (25°C) by rubbing the bottle between hands until the solution is clear. This has no impact on the product quality or effectiveness.

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 642 646

For further information visit our website

www.rejuvenail.com.au

AUST R 197723

RejuveNail® Anti-fungal nail lacquer is supplied in New Zealand by:

A. Menarini New Zealand Pty Ltd

P O Box 90296

Victoria Street West

Auckland 1142

Customer Information: 0800 102 349

This leaflet was prepared in March 2017.

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