

# Batrafen<sup>®</sup> Nail Lacquer (bat-rar-fen)

*Ciclopirox (sick-low-pir-rocks)*

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**Consumer Medicine Information (CMI)**

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## What is in this leaflet

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This leaflet answers some common questions about Batrafen Nail Lacquer.

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 or pharmacist has weighed the risks of you using it against the benefits they expect it will have for you.

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

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

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## What Batrafen Nail Lacquer is used for

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Batrafen Nail Lacquer is a nail lacquer that is painted onto the fingernails or toenails. Batrafen Nail Lacquer contains ciclopirox, which is an antifungal agent. Batrafen Nail Lacquer is used to treat fungal infections of the fingernails and toenails.

Fungal nail infections are hard to treat and a full cure depends on several factors, including how badly damaged the nail is. While Batrafen 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.

**Ask your doctor or pharmacist if you have any questions about why it has been recommended for you.**

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## Before you use it

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### ***When you must not use it***

**Do not use Batrafen Nail Lacquer if you are allergic to it or any of the ingredients listed at the end of this leaflet.**

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

**Do not give Batrafen Nail Lacquer to a child or adolescent.**

There is no experience with its use in children or adolescents under 18 years old.

**Do not use it if you are pregnant or intend to become pregnant.**

It may affect your developing baby if you use it during pregnancy.

**Do not use it if you are breast-feeding or planning to breast-feed.**

Batrafen Nail Lacquer may pass into breast milk and there is a possibility your baby may be affected.

**Do not use it 6 months after opening.**

**Do not use it after the expiry date (EXP) printed on the pack.**

If you use it after the expiry date has passed, it may not work as well.

**Do not use it if the packaging is torn or shows signs of tampering.**

### ***Before you start to use it***

**Tell your doctor or pharmacist if you have allergies to:**

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes.

**Tell your doctor or pharmacist if you have a history of diabetes or problems with your immune system.**

In this situation, fungal infections may be serious. Your doctor will discuss the best treatment for you.

**Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.**

Like most medicines of this kind, Batrafen Nail Lacquer is not recommended to be used during

pregnancy. Your doctor or pharmacist will discuss the risks and benefits of using it if you are pregnant.

**Tell your doctor or pharmacist if you are breast-feeding or planning to breast-feed.**

It is not known whether Batrafen Nail Lacquer passes into breast milk. Your doctor or pharmacist will discuss the risks and benefits of using it if you are breast-feeding or planning to breast-feed.

**Tell your doctor or pharmacist if you plan to have surgery.**

**If you have not told your doctor or pharmacist about any of the above, tell them before you use Batrafen Nail Lacquer.**

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

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

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## How to use it

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### ***How to use it***

**Unless otherwise directed, apply Batrafen Nail Lacquer in a thin layer every other day for the first month to all toenails and/or affected fingernails using the applicator brush provided.**

Unless otherwise directed, the number of applications may be reduced to not less than twice weekly in the second month of treatment, and to once weekly from the third month of treatment onwards.

**Remove the entire coating of lacquer once a week with commercial nail varnish remover. At the same time, remove as much as possible of the affected nail material using a nail file.**

If the coating of lacquer is damaged in the meantime, it is fine to paint over the chipped areas again with Batrafen Nail Lacquer.

It is not known if cosmetic nail varnishes are compatible with Batrafen Nail Lacquer. Use of cosmetic nail varnishes, while treating your nails with Batrafen Nail Lacquer, is not recommended.

### **When to use it**

If you are not sure when to use it, ask your doctor or pharmacist.

### **How long to use it**

Batrafen Nail Lacquer should not be used for more than six months.

You may not see an immediate improvement in the appearance of your nail.

Continue using Batrafen Nail Lacquer until your nails have regrown and look clear or almost clear.

Ask your doctor or pharmacist if you are not sure how long to use the medicine for.

### **If you forget to use it**

Apply it as soon as you remember, and then go back to using the lacquer as you would normally.

Do not use a double dose to make up for the dose you have missed. 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.

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

### **If you use too much (overdose)**

Immediately telephone your doctor, or the Poisons Information Centre (0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have used too much Batrafen Nail Lacquer.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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## **While you are using it**

### **Things you must do**

Tell all the doctors, dentists and pharmacists who are treating you that you are using Batrafen Nail Lacquer.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Batrafen Nail Lacquer.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are using this medicine.

If you become pregnant while you are using this medicine, stop using it and tell your doctor or pharmacist immediately.

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

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

Do not put it inside the mouth or vagina.

Be careful not to get it in your eyes.

Your eyes may become irritated if you touch them after applying Batrafen Nail Lacquer to your fingernails. If this happens, rinse your eyes with clean water and tell your doctor or pharmacist.

Never swallow this medicine.

Do not use more than the recommended dose unless your doctor or pharmacist tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop using Batrafen Nail Lacquer without checking with your doctor or pharmacist.

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## **Side effects**

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are

not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Batrafen Nail Lacquer.**

It helps most people with fungal infections of the fingernails and toenails, 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 usually short-lived.

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

Other side effects not listed above may occur in some consumers.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

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## **After using it**

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

## **Storage**

**Keep your nail lacquer bottle in the carton to protect it from exposure to light.**

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

**Discard 6 months after opening.**

**To prevent the solution from drying up, screw the cap firmly down after use.**

**To prevent the screw cap from sticking to the bottle, avoid spilling solution on the screw thread.**

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

**Do not leave it in the car.**

Heat and damp 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.

## **Disposal**

**Discard 6 months after opening.**

**If your doctor or pharmacist tells you to stop using Batrafen Nail Lacquer, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.**

**Return any unused medicine to your pharmacist.**

- butyl ester of PVM/MA copolymer
- ethyl acetate
- propyl alcohol.

Batrafen Nail Lacquer does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

## **Manufacturer/Sponsor**

Batrafen Nail Lacquer is made in Germany.

Batrafen Nail Lacquer is supplied in New Zealand by:

sanofi-aventis new zealand limited  
Level 8, James and Wells Tower  
56 Cawley Street  
Ellerslie  
Auckland

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## **Product description**

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

Batrafen Nail Lacquer is a clear, slightly yellow liquid.

Batrafen Nail Lacquer is supplied in a bottle with a screw cap and an applicator brush.

### ***Ingredients***

Active Ingredient:

- ciclopirox 80mg/g

Inactive Ingredients: