

CURANAIL[®]

5% W/V MEDICATED NAIL LACQUER

AMOROLFINE

PACKAGE LEAFLET: INFORMATION FOR THE USER

Curanail 5% w/v Medicated Nail Lacquer

Amorolfine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve within 3 months.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

- What is in this leaflet**
1. What Curanail is and what it is used for
 2. What you need to know before you use Curanail
 3. How to use Curanail
 4. Possible side effects
 5. How to store Curanail
 6. Contents of the pack and other information

1. What Curanail is and what it is used for

- Curanail is used to treat fungal infections affecting up to 2 nails and affecting the upper half or sides of the nail (as shown in the first picture below). If the infection appears to be more like pictures 2 or 3, you should consult your doctor.
- The active substance in Curanail is amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals.
- Amorolfine kills a wide variety of fungi that can cause nail infections. A fungal nail infection is likely to result in discoloured (white, yellow or brown), thick or brittle nails, although their appearance can vary considerably as the following pictures show:



2. What you need to know before you use Curanail

- Do not use Curanail if you are:**
- Allergic (hypersensitive) to amorolfine or any of the other ingredients of this medicine (listed in section 6).
 - Under the age of 18.

- Warnings and precautions**
- Take special care with Curanail:
- if you suffer from diabetes.
 - if you are being treated because you have a weak immune system.
 - if you have poor circulation in your hands and feet.
 - if your nail is severely damaged or infected.
 - if you get Curanail in your eyes or ears wash it out with water immediately and contact your doctor, pharmacist or nearest hospital straight away.
 - Avoid the lacquer coming into contact with mucous membranes (e.g. mouth and nostrils). Do not inhale.
 - Wear impermeable gloves when using organic solvents to stop the nail lacquer from being removed.

Using other medicines

You can use the nail lacquer whilst you are taking other medicines.

Using other nail products

Nail varnish or artificial nails should not be used while using Curanail.

Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

You should not use Curanail and tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding. Your doctor will then decide whether you should use Curanail.

Ask your doctor or pharmacist for advice before taking any medicine.

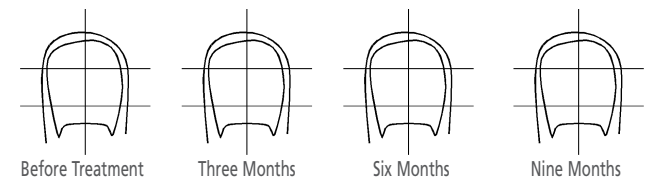
3. How to use Curanail

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and the Elderly

Before Commencing Treatment:

In the diagram below, shade the area affected by the fungal nail infection. This will help you in remembering how the nail looked originally when your treatment is reviewed. Every three months, shade the area now affected until the infected nail has completely grown out. If more than one nail is affected, select the worst affected nail for this exercise. Take this leaflet to the pharmacist or podiatrist when treatment is being reviewed to inform them of treatment progress to date.



- Instructions for use:**
- Treat your infected nails as described below. **NAILS SHOULD BE TREATED ONCE A WEEK.**
 - Once weekly application should continue for 6 months for finger nails and 9 to 12 months for toe nails.
 - Nails grow slowly so it may take 2 or 3 months before you start to see an improvement. It is important to carry on using the nail lacquer until the infection has cleared and healthy nails have grown back.
 - The following steps should be followed carefully for each affected nail:



Step 1: Prepare the Nail

Using a new file, gently file down the infected areas of nail, including the nail surface. Protect any healthy nails while you are doing this so that you don't spread the infection. **CAUTION:** Do not use the same nail file for infected nails and healthy nails, as this could spread the infection as well. To prevent the spread of infection take care that no one else uses the files from your kit.



Step 2: Clean the nail

Use one of the swabs provided, to clean the nail surface. Do not throw the swab away as you will need it later to clean the applicator.



Step 3: Treat the nail

Dip one of the re-usable applicators into the bottle of nail lacquer. The lacquer must not be wiped off on the edge of the bottle before it is applied. Apply the lacquer. Apply the nail lacquer evenly over the entire surface of the nail. Allow to dry. Let the treated nail(s) dry for approximately 3 minutes.

Step 4: Clean the applicator

You can use the applicators provided more than once. However, it is important to clean them thoroughly each time so that you don't spread the infection. Use the same swab you used for cleaning your nails. Don't touch the newly treated nails with the swab. Close the nail lacquer bottle tightly. **Dispose of the swab carefully as it is inflammable.**

- Before using the nail lacquer again, first remove the old lacquer from your nails using a swab, then file down the nails again if necessary.
- Re-apply the lacquer as described above.
- When dry the nail lacquer is unaffected by soap and water, so you can wash your hands and feet as normal. If you need to use chemicals such as paint thinners or white spirit, rubber or other impermeable (waterproof) gloves should be worn to protect the lacquer on your fingernails.
- It is important to carry on using the nail lacquer until the infection has cleared and healthy nails have grown back. This usually takes 6 months for fingernails and 9 to 12 months for toenails. You will see a healthy nail growing as the diseased nail grows out.



Before treatment



After treatment

If you accidentally swallow Curanail

If you, or anyone else, accidentally swallows the lacquer contact your doctor, pharmacist or nearest hospital straight away.

If you forget to use Curanail

Do not worry if you forget to use the lacquer at the right time. When you remember, start using the product again, in the same way as before.

If you stop using Curanail

Do not stop using Curanail before your doctor tells you to or your infection could come back. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Rare side effects (occurring in less than 1 in 1000 people)

Your nail may become discoloured, broken or brittle.

Very rare side effects (occurring in less than 1 in 10,000 people)

A burning sensation may occur in the area around the nail.

Unknown frequency of occurrence

Redness, itching, hives, blisters and allergic skin reaction (contact dermatitis).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Curanail

- Keep out of the sight and reach of children.
 - Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
 - Keep the pack away from heat and do not store above 30°C. Keep the bottle tightly closed after use.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Curanail contains

The active substance is amorolfine. Curanail contains 50 mg/ml (5%) of amorolfine (equivalent to 6.4% amorolfine hydrochloride). The other ingredients are ammonio methacrylate copolymer A, triacetin, butyl acetate, ethyl acetate and ethanol.

What Curanail looks like and contents of the pack

Each pack consists of 1 bottle filled with 3ml of Curanail nail lacquer together with cleansing swabs, reusable applicators and nail files.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Galderma (UK) Ltd, Meridien House, 69-71 Clarendon Road, Watford, Herts, WD17 1DS, United Kingdom. (PL 10590/0049).

Manufacturer: Laboratoires Galderma, ZI-Montdésir, 74540 Alby-Sur-Chéran, France.

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