

# 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 because it contains important information for you.**

This medicine is available without prescription. However, you still need to use Curanail carefully to get the best results from it.

- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Curanail is and what it is used for
2. Before you use Curanail
3. How to use Curanail
4. Possible side effects
5. How to store Curanail
6. Further 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. Before you use Curanail

**Do not use Curanail if you are:**

- Allergic (hypersensitive) to amorolfine or any of the other ingredients of Curanail (see section 6 for other ingredients).
- Pregnant, planning to become pregnant or are breast feeding.
- Under the age of 18.

**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.

**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.

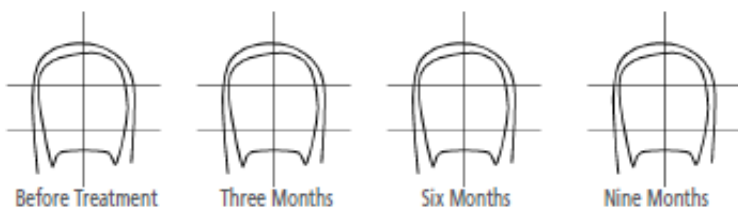
### 3. How to use Curanail

Always use Curanail exactly as your doctor or pharmacist has told you. You should 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 nail 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 same file.



##### Step 2: Clean the nail

Use an alcohol swab, or nail varnish remover, 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 product, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, Curanail 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 or it may become loose or start to separate from the nail bed.

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

A burning sensation or allergic skin reaction (contact dermatitis) may occur in the area around the nail.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **5. How to store Curanail**

- Keep out of the reach and sight of children.
- Do not use Curanail 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. Further information**

#### **What Curanail contains**

Curanail contains 50 mg/ml (5%) of the active substance 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 reuseable applicators.

#### **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.

**This leaflet was last approved in 07/2009.**