

<b>PATIENT INFORMATION LEAFLET</b>
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**LOCERYL® 5 %**

**Read all this leaflet carefully because it contains important information for you.**

This medicine is available without a doctor's prescription for you to treat a mild infection.

Nevertheless you still need to use LOCERYL 5 % 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 see a doctor if your symptoms worsen or do not improve.

1. Schedule 1

2. **LOCERYL 5 %** nail lacquer  
(amorolfine)

3. **WHAT LOCERYL 5 % CONTAINS**

- LOCERYL 5 % nail lacquer contains 50 mg/ml of the active ingredient amorolfine.
- The other ingredients are butyl acetate, ethanol absolute, ethyl acetate, methacrylic acid copolymer and triacetin.

#### **4. WHAT LOCERYL 5 % IS USED FOR**

LOCERYL 5 % nail lacquer belongs to a group of medicines known as antifungals. It kills a wide variety of fungi that can cause nail infections.

LOCERYL 5 % nail lacquer is used to treat fungal infections of the nails.

#### **5. BEFORE YOU USE LOCERYL 5 %**

##### **Do not use LOCERYL 5 %:**

- If you are hypersensitive (allergic) to amorolfine or any of the other ingredients of LOCERYL 5 %.
- If you have shown hypersensitivity to the treatment do not reuse LOCERYL 5 %.
- If you are pregnant or breastfeeding.
- Children must not be treated with LOCERYL 5 %.

##### **Take special care with LOCERYL 5 %:**

- Do not use nail varnish or artificial nails during treatment with LOCERYL 5 % nail lacquer.
- The nail lacquer is not affected by soap and water, so you may wash your hands and feet in the normal way.
- If you need to use chemicals such as white spirit or paint thinners, you must wear rubber gloves; otherwise the nail lacquer will dissolve.
- Due to the very low systemic absorption of amorolfine after using the nail lacquer a risk to the foetus appears to be negligible

### **Pregnancy and Breast-feeding:**

You should not use LOCERYL 5 % nail lacquer if you are pregnant or breast feeding.

### **Using other medicines with LOCERYL 5 %:**

If you are using other medicines on a regular basis, including complementary or traditional medicines, the use of LOCERYL 5 % nail lacquer with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

## **6. HOW TO USE LOCERYL 5 %**

### **1. File the nail**



File the affected nails, especially the diseased parts of the nail surface using the nail file provided.

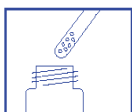
**CAUTION:** Use only the files in the treatment kit. Never file a healthy nail with a file used for diseased nails, otherwise you may spread the infection. To prevent the spread of infection take care that no one else uses the files from your kit.

### **2. Clean the nail**



Using one of the swabs provided wipe the entire surface of the affected nail(s) and remove any previous coat of the nail lacquer.

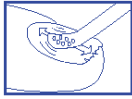
### **3. Take some lacquer from the bottle**



Dip the applicator into the bottle of nail lacquer.

The lacquer must not be wiped off the applicator on the edge of the bottle before it is applied.

#### 4. Apply the lacquer



Apply the lacquer evenly over the entire surface of the nail. Repeat steps 3 and 4 each affected nail.

#### 5. Allow to dry



Let the treated nail(s) dry for approximately three to five minutes.

#### 6. Clean the applicator



The applicator provided is re-usable. However, it is important to clean it thoroughly after completing each treatment procedure, using the same swab you used for nail cleansing. Avoid touching newly treated nails with the swab.

#### 7. Close the nail lacquer bottle tightly and throw away the used swab.



The nail lacquer must be applied to the affected finger or toenails once or twice weekly.

Every step of the treatment procedure is important. For a successful cure you must repeat each of the steps every time you treat your nails.

These measures and precautions may appear fussy; however, they are indispensable because they speed up healing and prevent healthy nails from becoming infected.

Remember: Successful treatment depends on your patience and perseverance.

It is important to carry on using LOCERYL 5 % 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.

**If you swallow LOCERYL 5 %:**

If you accidentally swallow the lacquer contact your doctor or pharmacist straight away. If neither is available, seek help at the nearest hospital or poison control center.

**7. POSSIBLE SIDE-EFFECTS**

LOCERYL 5 % nail lacquer can have side-effects.

- You may feel a slight burning in the nail area after applying the nail lacquer.
- Nail discolouration, broken nails, brittle nails may occur during treatment with LOCERYL 5 % nail lacquer. However, these reactions can also be linked to the onychomycosis itself.
- Contact dermatitis

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**8. STORING AND DISPOSING OF LOCERYL 5 %**

Keep all medicines out of the reach and sight of children.

Protect from heat.

Store below 30 °C.

Keep the container tightly closed.

Do not use after the expiry date stated on the carton and bottle label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

**9. PRESENTATION OF LOCERYL 5 %**

LOCERYL 5 % Nail Lacquer is available in a 2,5 ml and 5 ml bottle

Supplied with:

1 Applicator attached to the cap

30 Disposable nail files

30 cleansing swabs, impregnated with 70 % isopropyl alcohol in foil packs.

**10. IDENTIFICATION OF LOCERYL 5 %**

LOCERYL 5 % Nail Lacquer is a colourless to almost colourless clear liquid.

**11. REGISTRATION NUMBER**

27/13.9.2/0163

**12. NAME AND ADDRESS OF REGISTRATION HOLDER**

Galderma Laboratories South Africa (Pty) Ltd

17 Muswell Road South

Bryanston

2021

**13. DATE OF PUBLICATION**

23 July 2010