

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S1

### LYRECOL 5 % MEDICATED NAIL LACQUER

#### Amorolfine Hydrochloride

#### Read all of this leaflet carefully because it contains important information for you

LYRECOL 5 % medicated nail lacquer is available without a doctor's prescription, for you to treat a mild illness / maintain your health. Nevertheless, you still need to use LYRECOL 5 % medicated nail lacquer carefully to get the best results from it.

- Keep this leaflet. You may need to read it again;
- Do not share LYRECOL 5 % medicated nail lacquer with any other person;
- Ask your health care provider or pharmacist if you need more information or advice;
- You must see a doctor if your symptoms worsen or do not improve.

#### What is in this leaflet

1. What LYRECOL 5 % medicated nail lacquer is and what it is used for.
2. What you need to know before you use LYRECOL 5 % medicated nail lacquer.
3. How to use LYRECOL 5 % medicated nail lacquer.
4. Possible side effects.
5. How to store LYRECOL 5 % medicated nail lacquer.
6. Contents of the pack and other information.

#### 1. What LYRECOL 5 % medicated nail lacquer is and what it is used for

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GINA VAN DER WALT

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The active ingredient in LYRECOL 5 % medicated nail lacquer is amorolfine. LYRECOL 5 % medicated nail lacquer contains 50 mg/ml amorolfine.

LYRECOL 5 % medicated nail lacquer belongs to a group of medicines known as antifungals. It kills a wide variety of fungi that can cause nail infections. LYRECOL 5 % medicated nail lacquer is used to treat fungal infections of the nails.

## **2. What you need to know before you use LYRECOL 5 % medicated nail lacquer**

### **Do not use LYRECOL 5 % medicated nail lacquer:**

- If you are hypersensitive (allergic) to amorolfine or any of the other ingredients of LYRECOL 5 % medicated nail lacquer.

### **Warnings and precautions**

#### **Take special care with LYRECOL 5 % medicated nail lacquer:**

- Do not use nail varnish or artificial nails during treatment with LYRECOL 5 % medicated nail lacquer.
- After applying LYRECOL 5 % medicated nail lacquer, an interval of at least 10 min should be respected before application of any cosmetic nail lacquer. Before repeat application of LYRECOL 5 % medicated nail lacquer, the cosmetic nail lacquer should be removed carefully.
- LYRECOL 5 % medicated nail lacquer should not be applied on the skin around the nail.
- Avoid contact of the lacquer with eyes, ears and mucous membranes.
- If you need to use chemicals such as white spirit or paint thinners, you must wear rubber gloves; otherwise, the nail lacquer will dissolve.
- A systemic or local allergic reaction could possibly occur after use of LYRECOL 5 % medicated nail lacquer. If this happens, LYRECOL 5 % medicated nail lacquer should be stopped immediately, and medical advice should be sought.

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- Remove LYRECOL 5 % medicated nail lacquer carefully by using a nail remover solution. LYRECOL 5 % medicated nail lacquer should not be reapplied.

### **Children**

Do not use LYRECOL 5 % medicated nail lacquer in children.

### **Other medicines and LYRECOL 5 % medicated nail lacquer**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

No interaction studies have been performed. The use of artificial nails should be avoided during treatment with LYRECOL 5 % medicated nail lacquer.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using LYRECOL 5 % medicated nail lacquer.

You should not use LYRECOL 5 % medicated nail lacquer if you are pregnant or breastfeeding your baby.

### **Driving and using machines**

If LYRECOL 5 % medicated nail lacquer affect you in any way, do not drive, operate machinery or do anything that requires you to be alert.

It is not always possible to predict to what extent LYRECOL 5 % medicated nail lacquer may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which LYRECOL 5 % medicated nail lacquer affects you.

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### 3. How to use LYRECOL 5 % medicated nail lacquer

Do not share medicines prescribed for you with any other person.

Always use LYRECOL 5 % medicated nail lacquer exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

#### Treatment for fungal infection of the nail

LYRECOL 5 % medicated nail lacquer should be applied to affected finger or toenails once or twice weekly.

#### Method of administration

Apply LYRECOL 5 % medicated nail lacquer as follows:

##### Step 1:

Before the first application of LYRECOL 5 %, it is essential that the affected areas of nail (particularly the nail surfaces) should be filed down as thoroughly as possible using a disposable nail file supplied. The surface of the nail should then be cleansed and degreased using an alcohol-soaked swab (as supplied). Before repeating application of LYRECOL 5 %, the affected nails should be filed down again as required and must at all times first be cleansed with an alcohol-soaked swab to remove any remaining lacquer.

**Caution:** Nail files used for affected nails must not be used for healthy nails.

##### Step 2:

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With the applicator supplied, apply the nail lacquer to the entire surface of the affected nails and allow it to dry for approximately 3-5 minutes. For each nail to be treated, dip the applicator into the nail lacquer without wiping off any of the lacquer on the bottle neck. After use, clean the applicator with the same pre-soaked swab used before for nail cleansing.

**Keep the bottle tightly closed.**

### **Step 3:**

When working with organic solvents (thinners, white spirit, etc.) wear impermeable gloves in order to protect the LYRECOL 5 % on the nails.

Treatment should be continued without interruption until the nail is regenerated and the affected areas are finally cured. The required duration of treatment depends essentially on intensity and localisation of the infection and on growth rate of the nails, but in general, it is six months for fingernails and nine to twelve months for toenails.

### **Children**

LYRECOL 5 % medicated nail lacquer should not be used in children.

### **If you use LYRECOL 5 % medicated nail lacquer than you should**

In the event of overdosage, consult your doctor, pharmacist or nurse. If neither is available, contact the nearest hospital or poison centre.

### **If you forget to use LYRECOL 5 % medicated nail lacquer**

Do not use a double dose to make up for forgotten individual doses.

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#### 4. Possible side effects

LYRECOL 5 % medicated nail lacquer can have side effects.

Not all side effects reported for LYRECOL 5 % medicated nail lacquer are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using LYRECOL 5 % medicated nail lacquer, please inform your health care provider for advice.

If any of the following happens, stop using LYRECOL 5 % medicated nail lacquer and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- Rash or itching;
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to LYRECOL 5 % medicated nail lacquer. You may need urgent medical attention.

Tell your doctor or health care provider if you notice any of the following:

##### Less frequent:

- Skin burning sensation.
- Nail disorders.
- Nail discolouration.
- Broken nails.

##### Frequency unknown:

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- Superficial reddening of the skin, usually in patches, as a result of injury or irritation causing dilatation of the blood capillaries.
- Severe itching of the skin.
- A rash of round, red welts on the skin that itch intensely, sometimes with dangerous swelling, caused by an allergic reaction
- Blisters.
- Red, itchy rash caused by direct contact with a substance.

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

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of LYRECOL 5 % medicated nail lacquer.

### **5. How to store LYRECOL 5 % medicated nail lacquer**

Store all medicines out of sight and reach of children.

Store at or below 25 °C (room temperature).

Protect from heat. Keep bottle tightly closed after use.

Do not use LYRECOL 5 % medicated nail lacquer after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month. Do not use LYRECOL 5 % medicated nail lacquer after 6 months after first opening the bottle for use.

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Return all unused medicines to your pharmacist.

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

## 6. Contents of the pack and other information

### What LYRECOL 5 % medicated nail lacquer contains

- LYRECOL 5 % medicated nail lacquer contains 5 % w/v amorolfine in the form of hydrochloride. Each 1 ml of medicated nail lacquer contains 55,74 mg amorolfine hydrochloride (equivalent to 50 mg of amorolfine).
- The other ingredients are ammonio methacrylate copolymer A, triacetin, butyl acetate, ethyl acetate and ethanol.

### What LYRECOL 5 % medicated nail lacquer looks like

LYRECOL 5 % medicated nail lacquer is a clear and colourless solution, filled in glass bottles. The primary packaging material consists of a bottle made of hydrolytic class 1 or 3 (for 2,5 ml and 3,0 ml) and class 3 (for 5 ml) respectively. The cap is made of polyethylene (PE). Inside the cap there is a liner made of PTFE/PE/PTFE laminate.

Pack Sizes: 2,5 ml (1 x 2,5 ml)  
3,0 ml (1 x 3,0 ml)  
5,0 ml (1 x 5,0 ml)  
7,5 ml (1 x 2,5 ml & 1 x 5,0 ml)  
10,0 ml (2 x 5,0 ml)

Not all pack sizes may be marketed.

### Holder of Certificate of Registration

Trinity Pharma (Pty) Ltd.

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