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## Package Leaflet: Information for the User

### Amorolfine 5% w/v Medicated Nail Lacquer amorolfine (as hydrochloride)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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 Amorolfine Lacquer is and what it is used for
2. What you need to know before you use Amorolfine Lacquer
3. How to use Amorolfine Lacquer
4. Possible side effects
5. How to store Amorolfine Lacquer
6. Contents of the pack and other information

#### 1. What Amorolfine Lacquer is and what it is used for

- Amorolfine Lacquer is used to treat fungal infections of the nails.
- Amorolfine Lacquer contains the active ingredient amorolfine (as the hydrochloride) which belongs to a group of medicines known as anti fungals. It kills a wide variety of fungi that can cause nail infections.

#### 2. What you need to know before you use Amorolfine Lacquer

##### Do not use Amorolfine Lacquer if you are:

- Allergic (hypersensitive) to amorolfine or any of the other ingredients of Amorolfine Lacquer. Please check by reading the list of ingredients in section 6. If you answer yes, you must inform your doctor before starting treatment. Please seek immediate medical attention if you experience symptoms of an allergic reaction. Signs or symptoms of a severe allergic reaction may include a rash, with or without itching, swelling of the face, eyelids or lips and difficulty in breathing.

##### Warnings and precautions:

This medicine can cause allergic reactions, some can be serious. If this happens, stop applying the product, immediately remove the product with a nail varnish remover or the cleaning swabs provided with the package and seek medical advice. The product must not be reapplied.

You must get urgent medical help if you have any of the following symptoms:

- You have difficulty breathing
- Your face, lips, tongue or throat swell
- Your skin develops a severe rash

Talk to your doctor or pharmacist before using Amorolfine Lacquer

- Avoid the lacquer coming into contact with the eyes, ears or mucous membranes (e.g. mouth and nostrils).
- Do not inhale.
- Do not apply to the nail bed as it may cause localised effects such as contact dermatitis.
- Wear impermeable gloves when using organic solvents to stop the nail lacquer from being removed.

##### Other medicines and Amorolfine Lacquer

There are no known interactions with other medicines.

##### Using other nail products

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

### **Pregnancy and breast-feeding**

You should not use Amorolfine Lacquer 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 Amorolfine Lacquer. Ask your doctor or pharmacist for advice before taking any medicine.

## **3. How to use Amorolfine Lacquer**

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

Amorolfine Lacquer should be applied to the affected finger or toe nails once weekly.

### **Instructions for use:**

#### **Step 1: File the nail**

Before the first application, file down the infected areas of nail, including the nail surface, as much as possible using the nail file provided.

**CAUTION:** Do not use nail files used for infected nails on healthy 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.



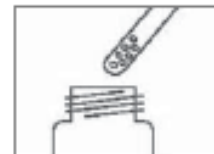
#### **Step 2: Clean the nail**

Use one of the swabs provided to clean the nail surface. Repeat steps 1 and 2 for each affected nail.



#### **Step 3: Take some lacquer from the bottle**

Dip one of the re-usable spatulas into the bottle of nail lacquer. The lacquer must not be wiped off on the edge of the bottle before it is applied.



#### **Step 4: Apply the lacquer**

Apply the nail lacquer evenly over the entire surface of the nail. Repeat steps 3 and 4 for each affected nail. Let the treated nail(s) dry for approximately 3 minutes.



#### **Step 5: Clean the spatula**

The spatulas provided are re-usable. However, it is important to clean them thoroughly after completing each treatment procedure, using the same swab you used for nail cleansing. Avoid touching 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 may 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.

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- It is important to carry on using Amorolfine 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.

Your doctor will probably check how your treatment is progressing every 3 months or so.

**If you get Amorolfine Lacquer in your eyes or ears**

If you get Amorolfine Lacquer in your eyes or ears wash out with water immediately and contact your doctor, pharmacist or nearest hospital straight away.

**If you accidentally swallow Amorolfine Lacquer**

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

**If you forget to use Amorolfine Lacquer**

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 Amorolfine Lacquer**

Do not stop using Amorolfine Lacquer 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, Amorolfine Lacquer can cause side effects, although not everybody gets them. In addition to the beneficial effects of Amorolfine Lacquer, it is possible that unwanted effects will occur during treatment, even when it is used as directed.

**Rare: may affect up to 1 in 1,000 people**

- Nail damages, nail discoloration, fragile or brittle nails.

**Very rare: may affect up to 1 in 10,000 people**

- Skin burning sensation

**Not known: frequency cannot be estimated from the available data**

- Systemic allergic reaction (a serious allergic reaction that can be associated with swelling of the face, lips, tongue or throat, difficulty breathing and/or a severe skin rash)
- Redness, itching, hives, blister, allergic skin reaction

**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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Amorolfine Lacquer**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and bottle. The expiry date refers to the last day of that month.
- Keep the pack away from heat (store below 30°C) and 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 to protect the environment.

#### **6. Contents of the pack and other information**

**What Amorolfine Lacquer contains**

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Each 1 ml of Amorolfine Lacquer contains 50 mg of the active substance amorolfine (as hydrochloride). The other ingredients are Eudragit RL 100 (ammonio methacrylate copolymer A), triacetin, butyl acetate, ethyl acetate and ethanol (anhydrous).

**What Amorolfine Lacquer looks like and contents of the pack**

Amorolfine Lacquer is a clear, colourless to pale yellow solution.

It is available in 2.5 ml, 3 ml and 5 ml packs; 1 bottle packed with or without cleansing swabs, spatulas and / or nail files. Amorolfine Lacquer is also available in 7.5 ml and 10 ml packs; 2 bottles packed with or without cleansing swabs, spatulas and / or nail files.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

The marketing authorisation holder is Bluefish Pharmaceuticals AB, P.O. Box 49013, 100 28 Stockholm, Sweden

The manufacturer is Chanelle Medical, Loughrea, Co. Galway, Ireland.

**This leaflet was last revised in:**