**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**AMOROLFINE 5% W/V NAIL LACQUER**

Read all of this leaflet carefully before you start using this medicine.

- 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 symptoms are the same as yours.
- 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 your pharmacist.

In this leaflet:
1. What Amorolfine 5% w/v is and what it is used for
2. Before you use Amorolfine 5% w/v
3. How to use Amorolfine 5% w/v
4. Possible side effects
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6. Further information

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### 1. WHAT AMOROLFINE 5% W/V IS AND WHAT IT IS USED FOR

- Amorolfine 5% w/v is used to treat fungal infections of the nails.
- Amorolfine 5% w/v contains the active ingredient amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals. It kills a wide variety of fungi that can cause nail infections.

### 2. BEFORE YOU USE AMOROLFINE 5% W/V

Do not use Amorolfine 5% w/v Nail Lacquer if you are:
- allergic (hypersensitive) to amorolfine or any of the other ingredients of Amorolfine 5% w/v (see section 6 for other ingredients).
- pregnant, planning to become pregnant or are breastfeeding.

Take special care with Amorolfine 5% w/v:
- if you suffer from diabetes.
- if you have or have had diabetes mellitus in your family.
- if your nail is severely damaged or infected.
- if you get Amorolfine 5% w/v 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 breathe it in.

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 Amorolfine 5% w/v.

Pregnancy and breast-feeding
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 5% w/v.

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

### 3. HOW TO USE AMOROLFINE 5% W/V

Always use Amorolfine 5% w/v exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Amorolfine 5% w/v Nail Lacquer should be applied to the affected finger or toe nail(s) once or twice a week exactly as directed by your doctor.

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 (or nail varnish remover) 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 applicators into the bottle of nail lacquer. The lacquer must not be wiped off the edge of the bottle before it is applied.
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 previously described.

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.

It is important to carry on using Amorolfine 5% w/v 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 accidentally swallow Amorolfine 5% w/v

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

If you forget to use Amorolfine 5% w/v

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 5% w/v

Do not stop using Amorolfine 5% w/v 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 5% w/v 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 AMOROLFINE 5% W/V

- Keep out of the reach and sight of children.
- Do not use Amorolfine 5% w/v after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
- Store below 30ºC. Protect from heat. Keep the bottle tightly closed and upright.
- This product is flammable! Keep the solution away from fire and flames!
- 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 Amorolfine 5% w/v contains:

Amorolfine 5% w/v contains 50 mg/ml (5%) of the active substance amorolfine (equivalent to 55.74 mg/ml amorolfine hydrochloride). The other ingredients are Eudragit RL 100 (ammonio methacrylate copolymer A), triacetin, butyl acetate, ethyl acetate and ethanol (anhydrous).

What Amorolfine 5% w/v looks like and contents of the pack

Amorolfine 5% w/v is a clear, colourless to pale yellow solution. It is available in 2.5 ml, 3 ml and 5 ml packs; 1 bottle with or without cleansing swabs, spatulas and / or nail files. Amorolfine 5% w/v 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 Chanelle Medical, Loughrea, Co. Galway, Ireland.

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

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