

Package Leaflet: Information for the User

Amorolfine 5% w/v Nail Lacquer

Amorolfine

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 only. 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 5% w/v is and what it is used for
2. What you need to know before you use Amorolfine 5% w/v
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4. Possible side effects
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6. Contents of the pack and other information

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. What you need to know 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 this medicine (listed in section 6).

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 5% w/v

- Children should not be treated with this product.
- The lacquer should not be applied on the skin around the nail.
- Avoid the lacquer coming into contact with the eyes, ears or mucous membranes (e.g. mouth and nostrils).
- Do not inhale.
- Wear impermeable gloves when using organic solvents to stop the nail lacquer from being removed.

Other medicines and Amorolfine 5% w/v

There are no known interactions with other medicines.

Using other nail products

Artificial nails should not be used while using Amorolfine 5% w/v.

Cosmetic nail varnish can be used, but you should wait at least 10 minutes after applying Amorolfine 5% w/v before painting your nails.

The nail varnish should be carefully removed before repeat application of Amorolfine 5% w/v

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, you should not use Amorolfine 5% w/v. Ask your doctor or pharmacist for advice before taking this medicine.

This medicine contains 482.53mg alcohol (ethanol) in 1ml, which is equivalent to 55.4% w/v



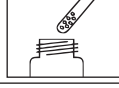

It may cause burning sensation on damaged skin.

3. How to use Amorolfine 5% w/v

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

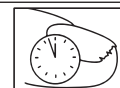
Amorolfine 5% w/v Nail Lacquer should be applied to the affected finger or toe nails once or twice a week exactly as directed by your doctor.

Instructions for use:

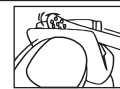
Step 1: File the nail Before the first application, file down the infected areas of nail, including the nail surface, as much as possible using the nail file provided. CAUTION: Do not use nail files used for infected nails on healthy nails, otherwise you may spread the infection. To prevent the spread 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 to clean the nail surface. Repeat steps 1 and 2 for each affected nail.	
Step 3: Take some lacquer from the bottle Dip the applicator into the bottle of nail lacquer. The lacquer must not be wiped off 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.	

Step 5. Allow to dry

Let the treated nail(s) dry for approximately 3 minutes.
Wait at least 10 minutes before applying cosmetic nail varnish.

**Step 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.
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 and any nail varnish 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.
- 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 get Amorolfine 5% w/v in your eyes or ears

If you get Amorolfine 5% w/v 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 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.

In addition to the beneficial effects of Amorolfine 5% w/v, it is possible that unwanted effects will occur during treatment, even when it is used as directed.

Stop using and seek immediate medical advice if you have any of the following:

- 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).

Rare: may affect up to 1 in 1000 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

- Redness, itching, hives, blisters and 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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Amorolfine 5% w/v

- 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 pack. 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.

This product is flammable! Keep the solution away from fire and flames!

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 protect the environment.

6. Contents of the pack and other information**What Amorolfine 5% w/v contains**

Amorolfine 5% w/v contains 50 mg/ml 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 packed 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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