



**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Amorolfine 5% w/v Medicated 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 Medicated nail lacquer is and what it is used for**
- ② **What you need to know before you use Amorolfine 5% w/v Medicated nail lacquer**
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① What Amorolfine 5% w/v Medicated nail lacquer is and what it is used for

Amorolfine 5% w/v Medicated nail lacquer is used to treat fungal infections of the nails.

The active ingredient of Amorolfine 5% w/v Medicated nail lacquer is 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 Medicated nail lacquer

Do not use Amorolfine 5% w/v Medicated nail lacquer if you are:

- allergic (hypersensitive) to amorolfine or any of the other ingredients of this medicine (see section 6 for other ingredients).

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 skins develops a severe rash.

Talk to your doctor or pharmacist before using this medicine.

- The lacquer should not be applied on the skin around the nail.
- Avoid the nail 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.

Using other medicines

There are no known interactions with other medicines.

Using other nail products

Artificial nails should not be used while using Amorolfine 5% w/v Medicated nail lacquer. Cosmetic nail varnish can be used, but you should wait at least 10 minutes after applying this medicine before painting your nails.

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

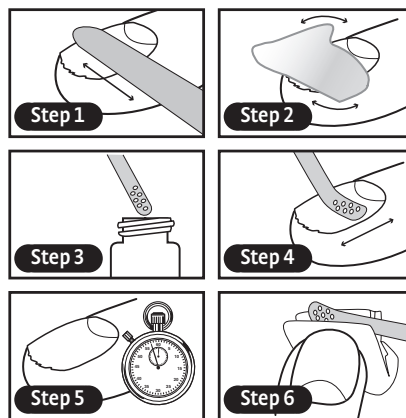
Pregnancy and breast-feeding

You should not use Amorolfine 5% w/v Medicated nail lacquer and tell your doctor if you are pregnant or planning to be pregnant or are breast-feeding. Your doctor will then decide whether you should use this medicine. Ask your doctor or pharmacist for advice before taking any medicine.

③ How to use Amorolfine 5% w/v Medicated nail lacquer

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 Medicated 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 one of the re-usable applicators 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.

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 applicators provided are re-useable. However, it is important to clean them thoroughly after 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 Amorolfine 5% w/v Medicated 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.
- It is important to carry on using Amorolfine 5% w/v Medicated nail lacquer until the infection has cleared and healthy nails have grown back. This usually takes 6 months for finger nails and 9 to 12 months for toe nails.

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

If you get Amorolfine 5% w/v Medicated nail lacquer in your eyes or ears

If you get Amorolfine 5% w/v Medicated nail 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 5% w/v Medicated nail 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 5% w/v Medicated nail lacquer

Don't worry if you forget to use Amorolfine 5% w/v Medicated nail 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 Medicated nail lacquer

Do not stop using Amorolfine 5% w/v Medicated nail 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, this medicine can cause side effects, although not everybody gets them. In addition to the beneficial effects of Amorolfine 5% w/v Medicated nail 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 discolouration, 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 the Yellow Card Scheme

(website: www.mhra.gov.uk/yellowcard).

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

⑤ How to store Amorolfine 5% w/v Medicated nail lacquer

Keep this medicine out of the sight and reach of children.

Do not use Amorolfine 5% w/v Medicated nail lacquer 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 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 Medicated nail lacquer contains

- The active substance is amorolfine (as hydrochloride). 1ml of nail lacquer contains 55.74mg amorolfine hydrochloride (equivalent to 50mg of amorolfine).
- The other ingredients are ammonio methacrylate copolymer A, triacetin, butyl acetate, ethyl acetate and ethanol.

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

Amorolfine 5% w/v Medicated nail lacquer is a clear colourless solution.

It is available as a 2.5, 5, 7.5 or 10ml pack.

Each 2.5ml and 5ml pack consists of 1 bottle filled with Amorolfine 5% w/v Medicated nail lacquer together with cleansing swabs, spatulas and nail files.

Each 7.5ml and 10ml pack consists of 2 bottles filled with Amorolfine 5% w/v Medicated nail lacquer together with cleansing swabs, spatulas and nail files.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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