

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.

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1 What Amorolfine Nail Lacquer is and what it is used for

Amorolfine Nail Lacquer contains the active substance amorolfine (as amorolfine hydrochloride), which belongs to a group of medicines known as antifungals. It kills a wide variety of fungi that can cause nail infections.

Amorolfine Nail Lacquer is used to treat fungal infections of the nails.

2 What you need to know before you use Amorolfine Nail Lacquer

Do not use Amorolfine Nail Lacquer:

- if you are allergic 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 varnish remover or the cleansing 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 Nail Lacquer

- 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.

Children and adolescents

Children should not be treated with Amorolfine Nail Lacquer owing to the lack of clinical experience available to date.

Other medicines and Amorolfine Nail Lacquer

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Using other nail products

Artificial nails should not be used while using Amorolfine Nail Lacquer.

Cosmetic nail varnish can be used, but you should wait at least 10 minutes after applying Amorolfine Nail Lacquer before painting your nails.

The nail varnish should be carefully removed before repeat application of Amorolfine Nail Lacquer.

Pregnancy and breast-feeding

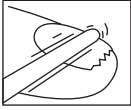

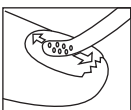


If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Your doctor will then decide whether you should use Amorolfine Nail Lacquer.

3 How to use Amorolfine Nail Lacquer

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

Amorolfine 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

	1. Before the first application of Amorolfine Nail Lacquer, carefully clean your nails: file down the affected area of the nail (particularly its surface) as completely as possible using the nail file provided. Take care not to file the skin around the nail.
	2. Clean the surface of the nail and remove any grease using the swabs provided.
	3. Apply the varnish using one of the reusable spatulas (provided in the carton) to the entire affected nail. Clean the reusable spatula between use on different nails, to avoid contaminating the varnish. Do not wipe the spatula on the edge of the bottle.
	4. Repeat the operations 1 to 3 for each affected nail.
	5. Clean the spatula using the swabs provided.
	6. Seal the bottle completely. Let the treated nail(s) dry for approximately 3 minutes.

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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.

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 Amorolfine 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 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 Nail Lacquer in your eyes or ears

If you get Amorolfine 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 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 Nail Lacquer

Don't worry if you forget to use Amorolfine 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 Nail Lacquer

Do not stop using Amorolfine 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 medicine, 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 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 discoloration, fragile or brittle nails.

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

- A burning sensation may occur in the area around the nail.

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, blisters, 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 Nail 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 pack after EXP. The expiry date refers to the last day of that month.

Protect from heat. Keep 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 protect the environment.

6 Contents of the pack and other information

What Amorolfine Nail Lacquer contains

- The active substance is amorolfine hydrochloride. 1 ml of Amorolfine Nail Lacquer contains amorolfine hydrochloride corresponding to 50 mg amorolfine.
- The other ingredients are: Ethanol anhydrous, Ammonio Methacrylate Copolymer (type A), Ethyl acetate, Butyl acetate, Triacetin.

What Amorolfine Nail Lacquer looks like and contents of the pack

Amber glass type I or type III bottle stopped with HDPE cap with a Teflon liner

Pack sizes: 2.5ml, 3ml, 5ml

All packs contain 30 cleansing swabs, 10 spatulas and 30 nail files.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord, Barnstaple, EX32 8NS, UK

Manufacturer

STRADIS, 29 Rue Léon Faucher, 51100 Reims, FRANCE

This leaflet was last revised in March 2019