



**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.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact your doctor if your symptoms worsen or do not improve within 3 months.
- 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 this medicine is and what it is used for
- ② What you need to know before you use this medicine
- ③ How to use this medicine
- ④ Possible side effects
- ⑤ How to store this medicine
- ⑥ Contents of the pack and other information

① What this medicine is and what it is used for

Amorolfine 5% w/v medicated nail lacquer is used to treat fungal infections affecting up to 2 nails and affecting the upper half or sides of the nail.

The active ingredient of this medicine is amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals.

Amorolfine kills a wide variety of fungi that can cause nail infections. A fungal nail infection is likely to result in discoloured (white, yellow or brown), thick or brittle nails, although their appearance can vary considerably.

② What you need to know before you use this medicine

Do not use this medicine if you are:

- Allergic to amorolfine or any of the other ingredients of this medicine (listed in section 6).
- Under the age of 18.

Warnings and precautions

This medicine can cause allergic reactions, although most are mild, 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.

Take special care with this medicine:

- If you suffer from diabetes.
- If you are being treated because you have a weak immune system.
- If you have poor circulation in your hands and feet.
- If your nail is severely damaged or infected.
- If you get this medicine 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 inhale.
- Wear impermeable gloves when using organic solvents to stop the nail lacquer from being removed.

Using other medicines

You can use the nail lacquer whilst you are taking other medicines.

Using other nail products

Artificial nails should not be used while using this medicine. 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 this product.

Tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without prescription.

Pregnancy and breast-feeding

You should not use this medicine 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 this medicine.

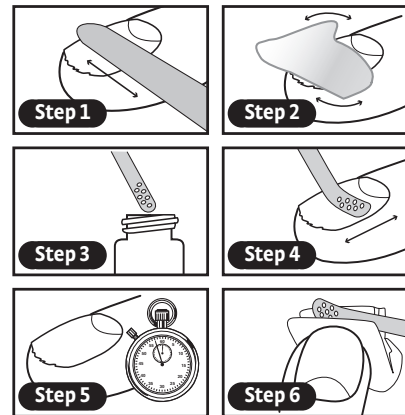
Ask your doctor or pharmacist for advice before taking any medicine.

③ How to use this medicine

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

Adults and the Elderly Instructions for use

- Treat your infected nails as described below.
- **Nails should be treated once a week.**
- Once weekly application should continue for 6 months for finger nails and 9 to 12 months for toe nails.
- Nails grow slowly so it may take 2 or 3 months before you start to see an improvement. It is important to carry on using the nail lacquer until the infection has cleared and healthy nails have grown back.
- The following steps should be followed carefully for each affected nail:



Step 1: File the nail

Using a new file, gently file down the infected areas of nail, including the nail surface. Protect any healthy nails while you are doing this so that you don't spread the infection.

CAUTION:

Do not use the same nail file for infected nails and 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. Do not throw the swab away as you will need it later to clean the applicator.

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.

Step 6: Clean the applicator

You can use the applicator provided more than once. It is important to clean it thoroughly after each application so that you don't spread the infection. Use the same swab you used for cleaning your nails. Do not put an unclean applicator into the bottle. 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 this medicine 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 this medicine 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. You will see a healthy nail growing as the diseased nail grows out.

If you get this medicine in your eyes or ears

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

If you accidentally swallow this medicine

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

If you forget to use this medicine

Don't worry if you forget to use the lacquer at the right time. When you remember, start using the medicine again, in the same way as before.

If you stop using this medicine

Do not stop using this medicine before your doctor or pharmacist 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.

Rare:

(may affect up to 1 in 1,000 people)

Nail damage, nail discolouration, fragile or brittle nails.

Very rare:

(may affect up to 1 in 10,000 people)

Skin burning sensation.

continued overleaf

**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 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 this medicine.

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 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 this medicine 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 this medicine looks like and contents of the pack

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

The pack is available as a 3ml bottle.

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

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Aspire Pharma Limited
Unit 4, Rotherbrook Court
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Petersfield
Hampshire GU32 3QG
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