



**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.
- 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.
- You must contact your doctor if you do not feel better (or if you feel worse) after 3 months.

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
- ⑦ General advice for people with fungal nail infections

① What this medicine is and what it is used for

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

This medicine is used to treat mild nail infections in adults aged 18 years and over.

Amorolfine kills a wide variety of fungi that can cause nail infections. Fungal nail infections can look very different, your nails could be discoloured (white, yellow or brown), thick or brittle.

This medicine is only suitable for mild infections (Picture 1). Talk to your doctor if the infection appears to be more like pictures 2 or 3.



Mild

Picture 1: Slight discoloration, nail may be slightly thicker and more brittle, affecting the upper half and edge of the nail.



Moderate

Picture 2: Large areas of the nail discoloured, nail likely to be thicker and more brittle.



Severe

Picture 3: Severe infection. Entire nail discoloured, thick and brittle. The surface of the nail may appear irregular, uneven, jagged and/or coarse.

② What you need to know before you use this medicine

Do not use this medicine if:

- your nail does not look similar to picture 1.
- you are allergic to amorolfine or any of the other ingredients of this medicine (listed in section 6).
- you are pregnant, might become pregnant, or are breast-feeding.
- your nail is moderately or severely damaged or infected (see pictures 2 and 3).

- you have poor blood circulation in your hands or feet.
- you have pain or swelling around the nail.
- you have more than 2 infected nails in total.
- you have a weak immune system.
- you are under the age of 18.
- you have diabetes.
- you have dark stripes running down the nail.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Amorolfine 5% w/v medicated nail lacquer.

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 re-applied.

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.

Do not apply this medicine on the skin around the nail.

Using other medicines

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines. This includes medicines obtained without a prescription, and herbal medicines. You can normally use this medicine when 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 medicine.

Pregnancy and breast-feeding

You should not use this medicine if you are pregnant, planning to become pregnant or are breast-feeding.

If you are pregnant, breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

③ How to use this medicine

Always use this medicine exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure.

Keeping a record

Before you start using this medicine you should keep a record of how your nail looks:

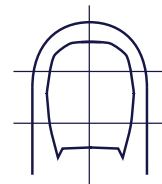
- Shade the area affected by the infection in the 'Before Treatment' diagram below.
- If you have 2 nails affected, just do this for your worst nail.
- Every 3 months, shade the area affected in the next diagram.
- Do this until the infected nail has completely grown out.

This will help you remember how your nail looked so you can see your progress.

Before treatment



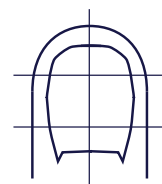
Three months



Six months



Nine months



How long to use

- You need to use this medicine once a week 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.
- You will see a healthy nail growing as the infected nail grows out.

- Nails grow slowly so it may take 2 or 3 months before you start to see an improvement.
- After every 3 months of treatment:
 - If the infection has improved, continue the treatment.
 - If the infection is the same or worse talk to your doctor or pharmacist. Take this leaflet with you.

The images below show examples of a nail at different time points during the course of treatment.



Before treatment



3 Months



6 Months

Safe use of this medicine

- If you get the medicine in your eyes or ears wash it out with water and talk to your doctor or pharmacist or go to the nearest hospital straight away.
- Do not let the medicine come into contact with your mouth or nostrils (or other 'mucous membranes').
- Do not inhale the medicine.
- Do not let anyone else use the files from your kit - this will stop the spread of infection.
- If you need to use chemicals such as paint thinners or white spirit when you have applied the medicine to your fingernails, wear rubber or other waterproof (impermeable) gloves. This will protect the medicine on your nails.

How to use – first use

Step 1: Prepare your nail



- Protect your healthy nails so that you don't spread the infection.
- Use a new file.
- Gently file down the

infected areas of your nail – including the nail surface.

- **Do not use the same nail file** for infected nails and healthy nails – this could spread the infection.

Step 2: Clean the nail



- Use one of the swabs provided.
- Clean the nail surface.
- **Do not throw the swab away** - you will need it

later to clean the applicator.

Step 3: Treat the nail



- Dip the applicator into the bottle of nail lacquer.
- **Do not wipe the lacquer off** on the edge of the bottle before it is applied.

- Apply the nail lacquer evenly over the entire surface of the nail.
- Allow it to dry - let the treated nail(s) dry for about 3 minutes. When the lacquer is dry it is not affected by soap and water. You can wash your hands or feet as normal. Wait at least 10 minutes before applying cosmetic nail varnish.

Step 4: Clean the applicator

- You can use the applicator provided more than once.
- It is important to clean it after each use - so you do not spread the infection.
- Use the same swab you used for cleaning your nails.
- Do not touch the newly treated nails with the swab.
- Close the nail lacquer bottle tightly.
- **Throw the swab away carefully as it will set on fire easily.**
- 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 fingernails and 9 to 12 months for toenails.

If the nail is still infected after this time you should see a doctor.

- If you do not continue using the nail lacquer every week the treatment may not work as expected and the fungus could also become resistant to the nail lacquer.

How to use – after first use

Each infected nail should be treated once a week.

- Before using the lacquer again, remove the old lacquer and any nail varnish from your nails using a swab.
- File down the nails again if needed.
- Re-apply the lacquer as described in Step 3 above.
- Clean the applicator as described in Step 4 above.

If you accidentally swallow this medicine

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

If you forget to use this medicine

Do not worry if you forget to use the lacquer exactly a week after the last time. When you remember, use the medicine again, in the same way as before.

You could use a diary to remind you.

If you stop using this medicine

Do not stop using this medicine until your nail improves. The images in 'How long to use' can help you understand what you are looking for.

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. The following side effects may happen with this medicine:

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

Nail damage, nail discoloured, 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 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 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
Bedford Road, Petersfield
Hampshire, GU32 3QG
United Kingdom

Manufacturer:

P.W.Beyvers GmbH
Schaffhausener Str. 26-34
D-12099 Berlin
Germany.

⑦ General advice for people with fungal nail infections

You can reduce your risk of developing a fungal nail infection by:

- keeping your hands and feet clean and dry.
- wearing well-fitting shoes made of natural materials and clean cotton socks - these will allow your feet to 'breathe'.
- clipping your nails to keep them short - don't share clippers or scissors with other people.
- not sharing towels and socks with other people - ensure you wash your towels regularly.
- not walking around barefoot in public pools, showers, or locker rooms - special shower shoes are available to protect your feet.
- replacing old footwear that could be contaminated with fungi.
- treating athlete's foot as soon as possible to stop the infection spreading to your nails.

Nail salon equipment can sometimes be the source of fungal nail infections. If you regularly visit a salon, make sure any equipment used is properly sterilised between uses.

This leaflet was last revised in 04/2021

1010549-P1.10