

PACKAGE LEAFLET: INFORMATION FOR THE USER

Amorolfine Apofri 5% 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 Apofri is and what it is used for
2. What you need to know before you use Amorolfine Apofri
3. How to use Amorolfine Apofri
4. Possible side effects
5. How to store Amorolfine Apofri
6. Contents of the pack and other information

1. What Amorolfine Apofri is and what it is used for

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

Amorolfine Apofri is used to treat fungal infections of the nails without involvement of the nail growth zone.

2. What you need to know before you use Amorolfine Apofri nail lacquer

Do not use Amorolfine Apofri

- if you are allergic to amorolfine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- Avoid contact of the lacquer with eyes, ears and mucous membranes.
- Nail files used for affected nails must not be used for healthy nails.
- If you are working with organic solvents (thinners, white spirit, etc.) you shall wear impermeable gloves in order to protect the Amorolfine Apofri on the nails.
- Do not use cosmetic nail lacquer or artificial nails during the treatment.

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 if:

- you have difficulty breathing
- your face, lips, tongue or throat swell
- your skin develops a severe rash

Children and adolescents

Amorolfin Apofri is not recommended for children and adolescents below the age of 18 years, due to lack of experience.

Other medicines and Amorolfin Apofri

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. It has not been investigated whether Amorolfin Apofri may interact with other medicines or not.

Pregnancy and breast-feeding

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

Experience with amorolfine use during pregnancy and breast-feeding is limited. Amorolfin Apofri should not be used during pregnancy and breast-feeding unless the doctor considers it clearly necessary.

Driving and using machines

Amorolfin Apofri does not affect your ability to drive or use machinery.

Amorolfin Apofri contains ethanol

This medicine contains 482.3 mg alcohol (ethanol) per ml. Ethanol may cause a burning sensation on damaged skin.

This product is flammable. Keep away from heat and open flame.

3. How to use Amorolfin Apofri

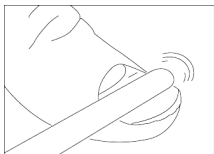
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose:

Adults (above 18 years)

Amorolfin Apofri should be applied to the affected nails once a week.

1. File the nail



File down the infected areas of nail, including the nail surface, as much as possible using a nail file provided in the pack.

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.

2. Clean the nail



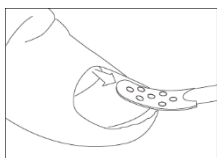
Use one of the swabs provided to clean the nail surface. Repeat steps 1 and 2 for each affected nail.

3. Take some lacquer from the bottle



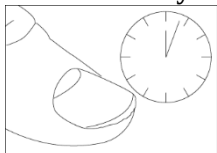
Dip one of the re-usable applicators into the bottle of nail lacquer. Do not wipe off the lacquer on the edge of the bottle before you apply it.

4. Apply the lacquer



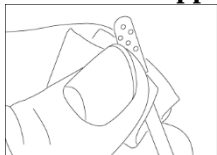
Apply the nail lacquer evenly over the entire surface of the nail. Repeat steps 3 and 4 for each affected nail.

5. Allow to dry



Let the treated nail(s) dry for approximately 3 minutes.

6. Clean the applicator



The applicators provided are re-useable. 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 the swab carefully as it is inflammable.

Before using Amorolfen Apofri again, first remove the old lacquer 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, you should wear rubber or other impermeable gloves to protect the lacquer on your fingernails.
- Do not use cosmetic nail lacquer or artificial nails during the treatment.

Important

- **Amorolfen Apofri shall only be applied on the nails.**
- **If you get Amorolfen Apofri in your eyes or ears wash 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.**
- **If you, or anyone else, accidentally swallows the medicated nail lacquer, contact doctor, hospital or straight away for risk assessment as well as advice.**

If you stop using Amorolfen Apofri

It may take time to treat fungal infections of the nails. You should use the nail lacquer every week for several months. It is important to carry on using Amorolfen Apofri until the infection has disappeared and healthy nails have grown back. It usually takes 6 months for fingernails and 9 to 12 months for toenails.

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.

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

- discolouration of the nail, become fragile or loose or start to separate from the nail bed.

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

- a burning sensation in the skin.

Frequency not known (cannot be estimated from the available data):

- redness of the skin, itching, contact dermatitis may occur in the area around the nail, hives or blisters.

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 national reporting system listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store Amorolfín Apofri

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

Keep the bottle tightly closed.

Do not use this medicine after the expiry date which is stated on the carton after Utg.dat. and on the bottle after EXP. The expiry date refers to the last day of that month.

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 Amorolfín Apofri contains

The active substance is amorolfine. 1 ml nail lacquer contains amorolfine hydrochloride corresponding to 50 mg amorolfine (5%).

The other ingredients are ethanol anhydrous, ammonio methacrylate copolymer A, ethyl acetate, butyl acetate and triacetin.

What Amorolfín Apofri looks like and contents of the pack

Amorolfín Apofri is a clear colourless nail lacquer.

Glass bottle with HPDE-cap with Teflon liner.

Pack sizes:

Glass bottle with 2.5 ml or 3 ml nail lacquer (not subject to medical prescription).

Glass bottle with 5 ml nail lacquer (subject to medical prescription).

The packs also contain 30 nail files, 10 spatulas and 30 swabs.

The swabs are impregnated with 70% isopropyl alcohol.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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[To be completed nationally.]
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