

PACKAGE LEAFLET

Package leaflet: Information for the patient
Amorolfine Viatris 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.

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, pharmacist or nurse have 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 talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What <Product name> is and what it is used for
2. What you need to know before you use <Product name>
3. How to use <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

1. What <PRODUCT NAME> is and what it is used for

<Product name> 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.

<Product name> is used to treat fungal infections of the nails.

2. What you need to know before you use <PRODUCT NAME>

Do not use <Product name>:

- 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 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:

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

Talk to your doctor or pharmacist before using <Product name>

- The lacquer should not be applied to 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 (waterproof) gloves when using organic solvents e.g. paint strippers, thinners, to stop the nail lacquer from being removed.

Children and adolescents

Due to the lack of clinical experience available to date, children should not be treated with <Product name>.

Other medicines and <Product name>

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 during treatment.

Cosmetic nail varnish can be used, but you should wait at least 10 minutes after applying <Product name> before painting your nails.

The nail varnish should be carefully removed before repeat application of <Product name>.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, 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 <Product name>.

<Product name> contains ethanol

This medicine contains 482.3mg alcohol (ethanol) in each mL. It may cause a burning sensation on damaged skin. Do not use near an open flame, lit cigarette or some devices (e.g. hairdryers) as it is flammable.

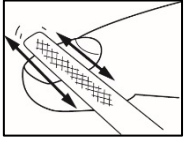
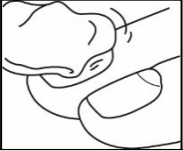
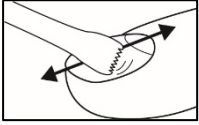
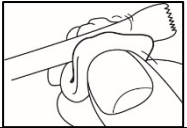
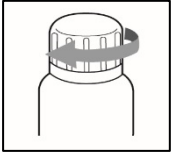
3. How to use <PRODUCT NAME>

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

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

<Product name> 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 <Product name>, 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 nail lacquer 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 nail lacquer. 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. Wait at least 10 minutes before applying cosmetic nail varnish.

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 flammable.

- Before using <Product name> again, first remove the old lacquer and any nail varnish 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 <Product name> 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 <Product name> in your eyes or ears

If you get <Product name> in your eyes or ears wash out with water immediately and contact

your doctor, pharmacist or nearest hospital straight away.

If you accidentally swallow <Product name>

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

If you forget to use <Product name>

Don't worry if you forget to use <Product name> at the right time. When you remember, start using the product again, in the same way as before.

If you stop using <Product name>

Do not stop using <Product name> 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.

Contact a doctor immediately if you experience any of the following side effects:

Not known (cannot be estimated from the available data):

- serious allergic reaction with symptoms that include feeling dizzy or faint, rash, itchy skin and swelling of the face, lips, tongue or throat that may cause difficulty breathing or swallowing

Other possible side effects:

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

- discoloured, broken or brittle nail

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):

- redness of the skin (erythema)
- itching of the skin (pruritus)
- allergic skin reaction (contact dermatitis)
- hives (urticaria) 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 [To be completed nationally] By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <PRODUCT NAME>

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 <Product name> contains

- The active substance is amorolfine hydrochloride. 1 ml of <Product name> contains amorolfine hydrochloride corresponding to 50 mg amorolfine.
- The other ingredients are ethanol anhydrous, ammonio methacrylate copolymer, ethyl acetate, butyl acetate and triacetin.

What <Product name> looks like and contents of the pack

Amber glass bottle with tamper-proof plastic cap containing a clear colourless solution.

Pack sizes: 2.5 ml, 3 ml, 5 ml

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer(s)

Farmaclair, 440 avenue du Général de Gaulle, 14200 Herouville Saint Clair, France.
Stradis, 29 rue Léon Faucher, 51100 Reims, France.

This medicine is authorised in the Member States of the European Economic Area under the following names:

Italy	Amorolfina Mylan Generics 5% Smalto medicate per unghie
Portugal	Amorolfina Mylan
Spain	Amorolfina Viatris 50 mg/ml barniz de uñas medicamentoso EFG
Sweden	Amorolfin Viatris 5% medicinskt nagellack

This leaflet was last revised in

2026-01-20