PACKAGE LEAFLET

Package leaflet: Information for the patient

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.

What is in this leaflet

1. What Amorolfine is and what it is used for

Amorolfine is used to treat fungal infections of the nails in adults. The active substance amorolfine prevents the growth of fungi and kills them.

Amorolfine acts against a whole range of amorolfine-susceptible fungal species, such as yeasts, skin fungi and moulds.
However, bacteria are not susceptible to amorolfine.

You must talk to a doctor if you do not feel better or if you feel worse after 3 months.

2. What you need to know before you use Amorolfine

Do not use Amorolfine

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

Warnings and precautions

Talk to your doctor or pharmacist before using Amorolfine if you have:

- diabetes
- a weak immune system, or are being treated to reduce its activity
- poor circulation in your hands and feet
- a severely damaged or infected nail
- if you have a history of nail injury, skin condition such as psoriasis, other chronic skin conditions, swelling, yellow nails combined with breathing disorders, painful nails, distorted/deformed nails or any other disorder around your nail.

During the application of amorolfine no cosmetic nail lacquer or artificial nails shall be used.

Avoid use of artificial nails during treatment with Amorolfine.
There is still no experience in patients with inflammatory changes surrounding the nail, diabetes, poor blood circulation, malnutrition, alcohol abuse or in children and infants.
Wear impermeable gloves when handling organic solvents, as the layer of Amorolfine on the fingernails will otherwise be removed.
Avoid contact of the lacquer with eyes, ears and mucous membranes. If you get Amorolfine in your eyes or ears wash it out with water immediately and contact your doctor or pharmacist.

Children and adolescents
Treatment of children and adolescents is not recommended due to a lack of experience.

Other medicines and Amorolfine
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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.
Amorolfine must not be used during pregnancy and breast-feeding unless your doctor indicates it clearly necessary.

Driving and using machines
Amorolfine has no influence on the ability to drive and use machines.

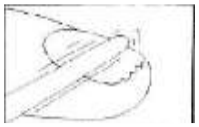
Amorolfine contains ethanol
This medicine contains 482.3 mg of alcohol (ethanol) in each ml of medicated nail lacquer. It may cause a burning sensation on damaged skin.

3. How to use Amorolfine

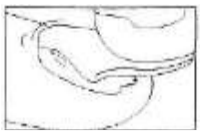
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For topical use. To be applied to the affected nails.
Apply Amorolfine once weekly to the affected finger- or toenails.

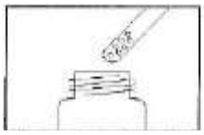
Observe the following instructions for use:



Each time before applying the nail lacquer, file down the diseased nail areas (especially nail surfaces) as much as possible with one of the nail files supplied.
Warning: Do not use a nail file used for the treatment of diseased nails for the care of healthy nails.



Then take a swab soaked in nail lacquer remover from its packaging. Use it to clean the surface of the diseased nails and remove the remaining lacquer residues. One swab is enough to clean all diseased nails. You can also use commercial nail varnish remover.



Dip the spatula supplied into the nail lacquer. Do not wipe it on the neck of the bottle. Dip the spatula once again for each diseased nail.

Apply the nail lacquer over the entire nail surface.

Carefully close the bottle immediately and clean the spatula using the swab soaked in nail lacquer remover.

Allow the applied nail lacquer to dry for about 3 to 5 minutes.

Before reusing the bottle, remove any lacquer residues on the nails and file your nails again. Clean your nails with the swab supplied and re-apply Amorolfine as prescribed.

Further tips on supporting your treatment
Hand towels should be washed as often as possible at a minimum of 60°C. Keep shoes well ventilated and allow them to dry.

Duration of treatment
Your treating doctor will decide how long you should use this medicine. Fungal infections are often very persistent. Therefore, use Amorolfine without interruption, until the diseased nails have

grown back completely healthy. For this, a period of 6 months is generally required for fingernails and 9 to 12 months for toenails.

However, **if there is no improvement after 3 months, you must consult your doctor.**

If you accidentally swallow Amorolfine
Contact your doctor, pharmacist or nearest hospital immediately if this occurs.

If you forget to use Amorolfine
When you remember, start using the product again, in the one week interval as before.

If you stop using Amorolfine
Do not stop using the lacquer before your doctor tells you, or your diseased nails have grown back completely healthy. If you stop too early 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.

Side effects may occur with following frequencies:

Uncommon, may affect up to 1 in 100 people
- allergic reaction.

Rare, may affect up to 1 in 1,000 people
- nail discolouration
- brittle or fragile nails.

Very rare, may affect up to 1 in 10,000 people
- burning of the skin.

Not known, frequency cannot be estimated from the available data
- skin reddening, itching
- skin inflammation on the application site
- nettle rash, 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 HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Amorolfine

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 carton and bottle label after EXP. The expiry date refers to the last day of that month.

2.5 ml and 3 ml bottle
After first opening: 6 months

5 ml bottle
After first opening: 9 months

Keep the container tightly closed. Keep the medicated nail lacquer away from fire or flames (the alcohol base is inflammable).
Discard the medicine if deteriorated, e.g. hardened.

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. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What Amorolfine contains
The active substance is: amorolfine in the form of hydrochloride.

Each ml contains 55.7 mg of amorolfine hydrochloride equivalent to 50 mg of amorolfine (5% w/v amorolfine).

Each bottle with 2.5 ml contains 139.3 mg of amorolfine hydrochloride equivalent to 125 mg of amorolfine.
Each bottle with 3 ml contains 167.1 mg of amorolfine hydrochloride equivalent to 150 mg of amorolfine.
Each bottle with 5 ml contains 278.5 mg of amorolfine hydrochloride equivalent to 250 mg of amorolfine.

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

What Amorolfine looks like and contents of the pack
Amorolfine is a medicated nail lacquer. It is a clear solution.

Amorolfine is packed in amber glass type I or type III bottles stopped with HDPE cap with a Teflon liner.

Pack sizes:
2.5 ml, 3 ml, 5 ml

All packs contain 30 alcohol cleansing swabs (soaked with isopropyl alcohol as nail lacquer remover and sealed in composite foil), 10 spatulas and 30 nail files.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Creapharm Industry, 29 rue Léon Faucher, 51100 Reims, France.
Farmaclair, 440 Avenue du Général de Gaulle, 14200 Hérouville Saint Clair, France.
Lek Pharmaceuticals d.d., Ulica 57, Verovškova 1526, Ljubljana, Slovenia.

This medicine is authorised in the Member States of the European Economic Area under the following names:
Austria: Amorolfin Laboratoires Gerda 50 mg/ml - wirkstoffhaltiger Nagellack
Ireland: Amorolfine 5% w/v, Medicated nail lacquer

This leaflet was last revised in 06/2023.