PACKAGE LEAFLET

Package leaflet: Information for the user

[Nationally completed name] 50 mg/ml medicated nail lacquer

amorolfine

[for POM:]
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.

[for OTC:]
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 talk to a doctor if you do not feel better or if you feel worse after 3 months.

What is in this leaflet

1. What {[Nationally completed name]} is and what it is used for

[Nationally completed name] is used to treat fungal infections of the nails in adults.
It should only be used if the upper half or sides of the nail are affected.
The active substance amorolfine prevents the growth of fungi and kills them.

[Nationally completed name] 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 [Nationally completed name]

Do not use [Nationally completed name]

- 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 [Nationally completed name] 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 [Nationally completed name].

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 [Nationally completed name] on the fingernails will otherwise be removed.

Avoid contact of the lacquer with eyes, ears or mucous membranes. If you get it in eyes or ears, immediately wash it out with water 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 [Nationally completed name]

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.
[Nationally completed name] must not be used during pregnancy and breast-feeding unless your doctor indicates it clearly necessary.

Driving and using machines
[Nationally completed name] has no influence on the ability to drive and use machines.

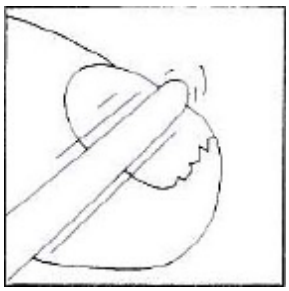
3. How to use [Nationally completed name]

[for OTC:]
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

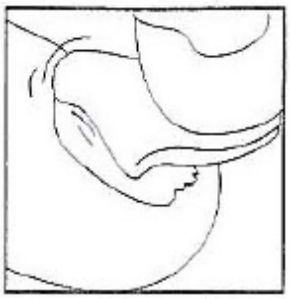
[for POM:]
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For topical use. To be applied to the affected nails.
Apply [Nationally completed name] once weekly to the affected finger- or toenails.

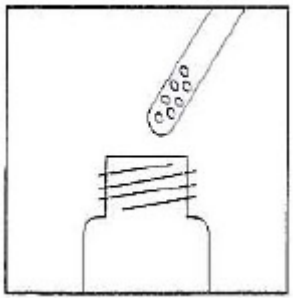
Observe the following instructions for use:



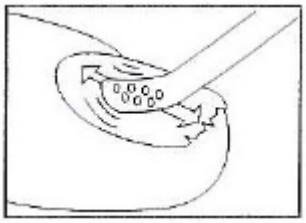
Each time before applying the nail lacquer, file down the diseased nail areas (especially nail surfaces) as much as possible with one of the nail files supplied.
Warning: Do not use a nail file used for the treatment of diseased nails for the care of healthy nails.



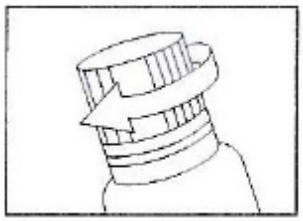
Then take a swab soaked in nail lacquer remover from its packaging. Use it to clean the surface of the diseased nails and remove the remaining lacquer residues. One swab is enough to clean all diseased nails. You can also use commercial nail varnish remover.



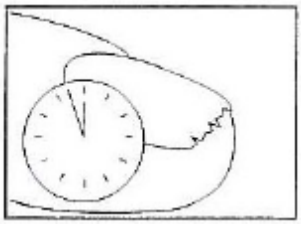
Dip the spatula supplied into the nail lacquer. Do not wipe it on the neck of the bottle. Dip the spatula once again for each diseased nail.



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 [Nationally completed name] 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
[for POM:]
Your treating doctor will decide how long you should use this medicine.

Fungal infections are often very persistent. Therefore, use [Nationally completed name] 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 [Nationally completed name]
Contact your doctor, pharmacist or nearest hospital immediately if this occurs.

If you forget to use [Nationally completed name]
When you remember, start using the product again, in the one week interval as before.

If you stop using [Nationally completed name]
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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [nationally completed 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 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 [nationally completed name] contains
The active substance is amorolfine in the form of hydrochloride.

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

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

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

What [nationally completed name] looks like and contents of the pack
[Nationally completed name] is a medicated nail lacquer. It is a clear solution.

[Nationally completed name] 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 Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Exorolfin 50 mg/ml - wirkstoffhaltiger Nagellack
Bulgaria: ЕКЗОРОЛФИН ЛАК 5% лечебен лак за нокти EXOROLFIN LAK 5% medicated nail lacquer
Czech Republic: EXOROLAK
Germany: Amorolfin - Gerda 50 mg/ml wirkstoffhaltiger Nagellack
Estonia: Exolorfin 50 mg/ml vaistinis nagų lakas
Greece: EXOROLFIN LAK
Croatia: EXOLAK 50 mg/ml ljekoviti lak za nokte

Hungary: EXOLORFIN 50 mg/ml gyógyszeres körömlakk
Ireland: Nailex 5% w/v, Medicated nail lacquer
Italy: Exolaq
Lithuania: Exolorfin 50 mg/ml vaistinis nagų lakas
Latvia: Exolorfin 50 mg/ml vaistinis nagų lakas
Romania: Exoderil 50 mg/ml, lac de unghii medicamentos
Slovenia: EXOLORFIN 50 mg/ml zdravilni lak za nohte
Slovak Republic: EXOROLFIN 5 %

This leaflet was last revised in {MM/YYYY}

[To be completed nationally]