

PATIENT INFORMATION LEAFLET

Amorolfine 5% w/v Medicated Nail Lacquer

FINROJ NL

Read all of this leaflet carefully before you start taking 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.

What is in this leaflet:

1. What FINROJ NL is and what it is used for
2. What you need to know before you take FINROJ NL
3. How to use FINROJ NL
4. What are the possible side effects of FINROJ NL
5. How to store FINROJ NL
6. Contents of the pack and other information

1. What FINROJ NL is and what it is used for

FINROJ NL is Amorolfine (as hydrochloride) Nail Lacquer which belongs to a group of medicines known as Antifungal. FINROJ NL is used to treat fungal infections of the nails. It kills a wide variety of fungi that can cause nail infections.

2. What you need to know before you use FINROJ NL

Do not use FINROJ NL:

- ❖ If you are allergic (hypersensitive) to amorolfine or any of the other ingredients of this medicine.

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 and seek medical advice. The product must not be reapplied.

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

Talk to your doctor or pharmacist before using FINROJ NL

- ❖ If you suffer from diabetes.
- ❖ If you are being treated because you have a weak immune system.
- ❖ If you have poor circulation in your hands and feet.
- ❖ If your nail is severely damaged or infected.
- ❖ If you get the medication on your eyes or ears. Wash it 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 breathe it in.

Precautions

- ❖ The lacquer should not be applied on the skin around the nail.
- ❖ Wear impermeable gloves when using organic solvents to stop the nail lacquer from being removed.

Other medicines and FINROJ NL

There are no known interactions with other medicines.

Using other nail products

Artificial nails should not be used while using FINROJ NL. Cosmetic nail varnish can be used in the treated nail but you should wait at least 10 minutes after applying FINROJ NL before painting your nails. The nail varnish should be carefully removed before repeat application of FINROJ NL. When organic solvents are used, impermeable gloves should be used otherwise FINROJ NL will be removed.

Pregnancy, breast-feeding and fertility

FINROJ NL should not be used during pregnancy and/or breast-feeding unless clearly necessary. 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 taking this medicine.

3. How to use FINROJ NL

Always use FINROJ NL 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.

FINROJ NL should be applied to the affected finger or toe nails once or twice a week exactly as directed by your doctor

Instructions for use:

Step 1: File the nail

Before the first application, file down the infected areas of nail, including the nail surface, as much as possible using a nail file.

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 used files.



Step 2: Clean the nail

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



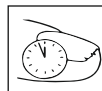
Step 3: Apply the lacquer

Dip the applicators into the bottle of nail lacquer. The lacquer must not be wiped off the edge of the bottle before it is applied. Apply the lacquer evenly over the entire surface of the nail. Repeat this step for each affected nail.



Step 4: Allow to dry

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



Step 5: Clean the applicator

The applicator provided is re-usable. However, it is important to clean them thoroughly after completing each treatment procedure, using the 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.



- ❖ Before using the nail lacquer again, first remove the old lacquer 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 can 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 the nail lacquer 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 diseased nail grows out.

If you get FINROJ NL in your eyes or ears

If you get FINROJ NL in your eyes or ears wash out with water immediately and contact your doctor, pharmacist or nearest hospital straight away.

If you accidentally swallow FINROJ NL

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

If you forget to use FINROJ NL

Do not worry if you forget to use the lacquer at the right time. When you remember, start using the product again, in the same way as before.

If you stop using FINROJ NL

Do not stop using FINROJ NL before your doctor tells you to or your infection could come back. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. What are the possible side effects of FINROJ NL

Like all medicines, FINROJ NL can cause side effects, although not everybody gets them. In addition to the beneficial effects of FINROJ NL, it is possible that unwanted effects will occur during treatment, even when it is used as directed.

Stop using and seek immediate medical advice if you have any of the following:

- ❖ 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).

Rare: may affect up to 1 in 1000 people

- ❖ Nail damages, nail discoloration, 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

- ❖ Redness, itching, hives, blisters and 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.

5. How to store FINROJ NL

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 (Store below 30°C) and 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 waste-water 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 FINROJ NL contains

FINROJ NL contains Amorolfine Hydrochloride IP equivalent to Amorolfine 5% w/v.

What FINROJ NL looks like and contents of the pack

FINROJ NL is a Clear colourless lacquer solution. It is available in 2.5 ml pack and filled in an amber coloured glass bottle with screw cap. Each filled bottle is packed in a printed paper carton along with applicator and packing insert.



Manufactured by :
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