

PATIENT INFORMATION LEAFLET
NACLER NAIL LACQUER

SCHEDULING STATUS:

S1

NACLER Nail Lacquer

Amorolfine as amorolfine hydrochloride

Read all of this leaflet carefully because it contains important information for you

NACLER is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use NACLER carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NACLER with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 6 months for fingernails and 9 to 12 months for toe nails.

What is in this leaflet

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

1. What NACLER is and what it is used for

NACLER contains amorolfine (as amorolfine hydrochloride), which belongs to a group of

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medicines known as antifungals.

It is used to treat fungal infections of the nails.

2. What you need to know before you use NACLER

Do not use NACLER:

- if you are hypersensitive (allergic) to amorolfine or any of the other ingredients of NACLER (see section 6)
- if you are pregnant or breastfeeding.

Children should not use NACLER.

Warnings and precautions

Take special care with NACLER. 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.

- Avoid NACLER coming into contact with your eyes, ears or mucous membranes (e.g. mouth and nostrils).
- Avoid using nail varnish or wearing artificial nails.
- Wear rubber gloves when using organic solvents such as white spirit or thinners, to stop NACLER from being removed.

Children:

Children – particularly young children and infants - should not be treated with NACLER (see do not use NACLER).

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Other medicines and NACLER

There are no known interactions with NACLER .

The use of nail varnish or artificial nails should be avoided during treatment with NACLER.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby,, please consult your doctor, pharmacist or other healthcare professional for advice before using NACLER.

You should not use NACLER if you are pregnant or breastfeeding your baby.

Driving and using machines

NACLER is not expected to interfere with your ability to drive or use machines.

3. How to use NACLER

Do not share medicines prescribed for you with any other person.

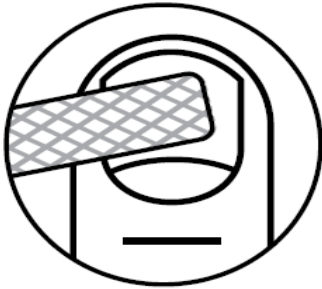
Always use NACLER exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

NACLER should be applied to the affected finger or toe nails once or twice weekly.

Instructions for use:

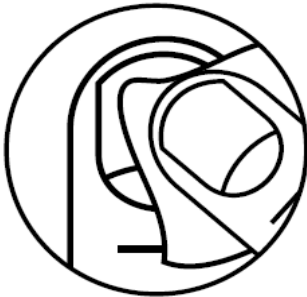
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1. File the infected nails, especially the diseased parts of the nail surface, to eliminate as much as possible of the diseased nail and the fungus affecting it.

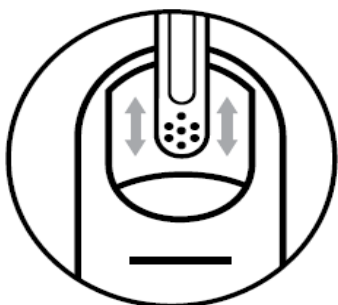
Caution: Use only the files in the treatment kit. Never file a healthy nail with a file used for diseased nails, otherwise you may spread the infection. Fungal infections are contagious; to prevent the spread of infection, take care that no other person uses the files from your kit.



2. Using one of the pre-soaked pads provided, wipe the entire surface of the infected nail(s). Take care to remove any previous coat of NACLER.

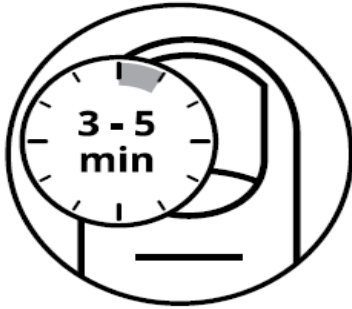


3. Dip one of the application spatulas into the bottle of NACLER without wiping off any of the lacquer on the bottle neck.



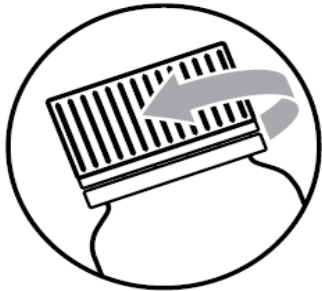
4. Apply NACLER evenly over the entire surface of the nail. Repeat steps 3 and 4 for each infected nail.

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5. Allow the nail(s) to dry for approximately 3 – 5 minutes.

6. The spatulas provided are reusable. However, it is important to clean them thoroughly after each treatment, using the same pre-soaked pad you used to clean the nail.



7. **Keep the bottle tightly closed** and throw away the used pad. NACLER is not affected by soap and water, so you may wash your hands and feet in the normal way. However, if you handle solvents such as white spirit or paint thinner, you must wear rubber gloves, otherwise

NACLER nail lacquer will dissolve.

Treatment should be continued without interruption until the infection has cleared and the nail has grown back and is healthy. Generally, it is 6 months for fingernails and 9 to 12 months for toe nails.

Consult your healthcare provider after 3 months of treatment. Co -existent athletes foot should be treated with an antifungal cream.

If you get NACLER in your eyes or ears

If you get NACLER in your eyes or ears wash out with water immediately and contact your

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doctor, pharmacist or nearest hospital straight away.

Your doctor will tell you how long your treatment with NACLER will last. Do not stop treatment early because your infection could come back.

If you have the impression that the effect of NACLER is too strong or too weak, tell your doctor or pharmacist.

If you use more NACLER than you should

No symptoms of overdose are expected following topical application of NACLER.

If you, or anyone else accidentally swallows NACLER, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use NACLER

If you forget to use NACLER, start using the lacquer again as soon as you remember, in the same way as before.

If you stop using NACLER

Do not stop using NACLER before your doctor tells you to, or your nail infection may return.

4. Possible side effects

NACLER can have side effects.

Not all side effects reported for NACLER are included in this leaflet. Should your general

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health worsen, or if you experience any untoward effects while using NACLER, please consult your healthcare provider for advice.

If any of the following happens, stop using NACLER and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to NACLER. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- discoloured, broken or brittle nails, nail damage.

Less frequent side effects:

- a skin burning sensation that occurs in the area around the nail
- rash, dry or cracked skin, itching

The following side effects have been reported but the frequency for them to occur is not known:

- redness, itching, hives, blisters and allergic skin reaction

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report any side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: <https://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of NACLER.

You can also send an email directly to the company,

pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store NACLER

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep bottle tightly closed, and in the carton until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NACLER contains

The active substance is amorolfine.

Each 1ml of nail lacquer contains amorolfine hydrochloride equivalent to 50 mg amorolfine base.

The other ingredients are:

Ammonio methacrylate copolymer Type A, ethanol anhydrous, ethyl acetate, n-butyl acetate and triacetin

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What NACLER looks like and contents of the pack

NACLER is a clear, colourless to pale yellow solution.

NACLER is supplied in a 2,5 ml amber glass bottle with white HDPE cap and PTFE liner with tamper evident ring, packed in an outer carton which also contains the following:

10 spatulas, 30 disposable nail files and 30 swabs.

Each bottle contains 2,5 ml.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

<https://www.mydynamics.co.za/>

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