

CURANAIL[®]

5% W/V MEDICATED NAIL LACQUER

AMOROLFINE

PACKAGE LEAFLET: INFORMATION FOR THE USER

Curanail 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.

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 your symptoms worsen or do not improve within 3 months.

What is in this leaflet:

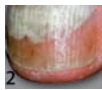
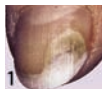
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1. WHAT Curanail 5% w/v Medicated Nail Lacquer IS AND WHAT IT IS USED FOR

CURANAIL 5% is an antifungal medicated nail lacquer (*medicine for treatment of infections caused by a microscopic fungus*).

CURANAIL 5% is used to treat **nail mycoses** (*infections caused by a fungus*) affecting **up to 2 nails** in adults. A mycosis generally results in nail discolouration (white, yellow or brown) and thickening, although the appearance may vary considerably.

If the infection is limited to the upper part of the nail as in photo 1 below, follow the advice of your **pharmacist**. If the infection appears to be more like photos 2 or 3, you should see your **doctor**.



2. WHAT YOU NEED TO KNOW BEFORE YOU USE Curanail 5% w/v Medicated Nail Lacquer

Do not use CURANAIL:

- if you are allergic (hypersensitive) to the active ingredient (amorolfine) or to one of the other ingredients of CURANAIL,
- if you are under 18 years old.

Warnings and precautions:

- Do not apply CURANAIL on the skin around the nail.
- Avoid all contact with your eyes, ears or mucous membranes.
- Owing to the lack of clinical experience to date, children should not be treated with CURANAIL.

***You must consult your physician:**

- If you suffer from diabetes,
- if you are being treated for an immune system disorder (disorder that reduces the body's defenses),
- if you have poor blood circulation in your hands and feet,
- 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.
- if your nail is severely damaged (over two thirds of the nail plate is affected) or infected. In these cases, your doctor may prescribe oral therapy as well as your medicated nail lacquer.
- During the application of amorolfine no cosmetic nail lacquer or artificial nails shall be used. When organic solvents are used impermeable gloves shall be used otherwise amorolfine nail lacquer will be removed.
- This product contains ethanol (alcohol). Using the product too often or applying inappropriately can cause irritation or dryness of the surrounding skin.

All medicines can cause allergic reactions; although most are mild, 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:

- You have difficulty breathing
- Your face, lips, tongue or throat swell
- Your skin develops a severe rash

Other medicines and CURANAIL:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

Experience with amorolfine use during pregnancy and/or lactation is limited. Amorolfine should not be used during pregnancy and/or lactation 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 Curanail 5% w/v Medicated Nail Lacquer?

Before starting treatment

Shade the nail surface affected by the infection **on the diagram** below. This will help you to remember how the nail originally looked when the efficacy of your treatment is reviewed. Every 3 months, shade the affected area until the infected nail has grown out completely. If two nails are infected, select the most infected nail.

Take this leaflet with you when you ask for the advice of your doctor or pharmacist.



Before Treatment



1 month



2 months



3 months



6 months

Posology

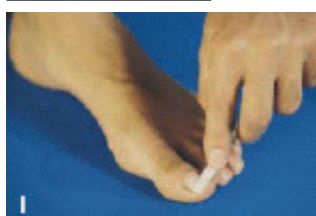
NAILS SHOULD BE TREATED ONCE A WEEK.

This treatment must be continued until the healthy nail has grown back, that is about 6 months for fingernails and 9 to 12 months for toenails.

Nails grow slowly, so it may take 2 to 3 months before an improvement is seen. It is important to continue using the lacquer until the infection has cleared and the healthy nail has grown back.

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

Method of administration



The **following steps** must be strictly followed for **each nail**.

Step 1: prepare the nail

Remove any former nail varnish with a nail varnish remover. With a new nail file, file the whole surface of the nail, especially the infected areas.

CAUTION: do not use the same nail file for healthy nails to avoid spreading the infection. Take care that no one else uses your files.



Step 2: clean the nail

Use one of the cleansing swabs provided in the pack to clean your nail. Keep the swab as you will need it later for cleaning the applicator.



Step 3: treat the nail

Dip the applicator into the bottle of lacquer. The lacquer must not be wiped off on the edge of the bottle. Apply the lacquer evenly over the whole surface of the nail. Let it dry for about 3 minutes.

Repeat the above procedures for **each infected nail**.

Before using the bottle **next time**, remove any remaining lacquer layers and file your nail again. Clean your nail with the cleansing swab and apply the lacquer once more as indicated above.

After each application of CURANAIL:

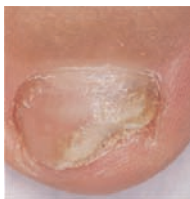
- To avoid contaminating other nails, the applicator must be carefully cleansed using the swab. Use the same swab that you used for cleaning your nail. Do not touch treated nails with the swab.
- Remove any lacquer which may be on the exterior of the stopper with one of the swabs provided.
- Close the bottle tightly.
- Dispose of the swab carefully as it is inflammable.
- Wash your hands carefully. However, when applying the lacquer to your fingernails, wait until it has completely dried before washing.

Warning

- Do not wear artificial nails during the whole treatment period.
- Wait until the lacquer is dry before washing your hands or feet. When the lacquer is dry, it is resistant to soap and water: you can therefore wash your hands and feet as usual.

Duration of treatment

It is important to carry on using the nail lacquer until the infection has cleared and a healthy nail has grown back. This takes about 6 months for fingernails and 9 to 12 months for toenails. You will see a healthy nail growing as the infected nail grows out.



Before treatment



After treatment

If there are no signs of improvement after 3 months of treatment, you should see your doctor.

IMPORTANT

- If you get CURANAIL, 5% in your eyes or ears, wash it out with water immediately and contact your doctor, your pharmacist or your nearest hospital straight away.
- Avoid the lacquer coming into contact with mucous membranes (e.g. mouth or nostrils). Do not inhale the lacquer.
- If you, or anyone else, accidentally swallow the lacquer, contact your doctor, your pharmacist or your nearest hospital straight away.

4. POSSIBLE SIDE EFFECTS

Like all medicines, CURANAIL 5%, medicated nail lacquer can have side effects, although not everybody gets them.

Some nail abnormalities (nail discolouration, fragile or brittle nails), skin burning sensations, redness, itching, hives, blisters and allergic skin reactions have been reported.

However, these abnormalities could be directly related to the nail infection.

Rare: may affect up to 1 in 1,000 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

- 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).
- Redness, itching, hives, blister, 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 directly via HPRA Pharmacovigilance, Earlsfort Terrace , IRL - Dublin 2, Tel: +353 1 6764971,

Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

5. HOW TO STORE Curanail 5% w/v Medicated Nail Lacquer

Keep this medicine out of the sight and reach of children.

Do not use CURANAIL 5%, medicated nail lacquer after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening: 6 months

Keep this medicine away from heat. Close the bottle tightly 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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What CURANAIL contains:

The active substance is:

Curanail medicated nail lacquer contains 50 mg/ml (5% w/v) of the active substance amorolfine (as amorolfine hydrochloride).

The other ingredients are:

methacrylic acid copolymer (EUDRAGIT RL100), triacetin, butyl acetate, ethyl acetate and ethanol anhydrous.

What CURANAIL looks like and contents of the pack

This medicine consists of 1 bottle filled with 1.25ml or 2.5ml of medicated nail lacquer together with an applicator integrated in the cap or separate applicators, cleansing swabs and nail files.

Marketing Authorisation Holder

GALDERMA INTERNATIONAL S.A.S.

TOUR EUROPLAZA

20 AVENUE ANDRÉ PROTHIN

LA DÉFENSE 4

92927 PARIS LA DÉFENSE CEDEX

FRANCE

(PA 22743/004/001)

Manufacturer

LABORATOIRES GALDERMA

ZI - MONTDESIR

74540 ALBY-SUR-CHERAN

FRANCE

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

France: Locerylpro

Ireland: Curanail

Italy: Onilaq

This leaflet was last revised in April 2019.

ADVICE AND RECOMMENDATIONS TO SUPPORT YOUR TREATMENT

Nail mycoses (onychomycosis): what are the risk factors?

Toe nails:

- repetitive minor nail or foot trauma, the toes being wrongly positioned.
- wearing closed shoes and/or plastic shoes or synthetic fibre socks, all of which encourage dampness.
- professions where boots or safety shoes are necessary as this can encourage perspiration.
- sports resulting in impact to the feet such as judo or running and barefoot sports such as swimming.

Finger nails:

- Check for a fungal foot infection (known as dermatophytosis).
- Repeated contacts with water (which can induce a type of mycosis known as candidiasis).
- Nail trauma or irritation through:
 - repetitive minor traumas (gardening...),
 - manual use of detergents (washing powders and liquids or other harsh products),
 - occupational exposure (hairdressers, manicurists, podiatrists).

Nail mycoses (onychomycosis): how to prevent and avoid contamination?

- **Disinfect** shoes and socks. Ask your pharmacist for advice if necessary.
- **Treat** all skin infections between the toes and of the feet (on the sole) as soon as possible.
- Use your own towel to **avoid contaminating** other people.
- **Dry** the spaces between your toes and the whole surface of your feet carefully, after you shower or bath, to avoid contaminating the other nails and the skin.

Nail mycoses (onychomycosis): why is it important to follow the treatment carefully?

For it to be effective, the treatment must be applied during **the whole period scheduled, without interruption, until your nail has grown out completely.**

DO NOT BE DISCOURAGED!

- The treatment may take 6 months for fingernails and 9 to 12 months for toenails.
- All treatments are long: to be effective the treatment must be continued until the nail has grown out completely.