

Mycofine 5% w/v Nail Lacquer

Amorolfine hydrochloride 5% w/v Nail Lacquer

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What *Mycofine* is used for

Mycofine is used to treat fungal infections of the nails.

Mycofine contains active ingredient amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals. It kills a wide variety of fungi that can cause nail infections.

How *Mycofine* works

Amorolfine from nail lacquer penetrates into and diffuses through the nail plate and is thus able to eradicate poorly accessible fungi in the nail bed. Systemic absorption of the active ingredient is very low with this type of application.

Before you use *Mycofine*

- When you must not use it

Do not use *Mycofine* if you are:

- Allergic (hypersensitive) to amorolfine or any of the other ingredients of *Mycofine*.

Please check by reading the list of ingredients in section 8. If you answer yes, you must inform your doctor before starting treatment. Please seek immediate medical attention if you experience symptoms of an allergic reaction. Signs or symptoms of a severe allergic reaction may include a rash, with or without itching, swelling of the face, eyelids or lips and difficulty in breathing.

- Pregnant, planning to become pregnant, or are breast-feeding.
- Do not use in children under 12 years of age. The safety and effectiveness of amorolfine in children have not been established.

Pregnancy and breast-feeding:

You should not use *Mycofine* and tell your doctor if you are pregnant, planning to become pregnant or are breast-

feeding. Your doctor will then decide whether you should use *Mycofine*.

Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it
Tell your doctor or pharmacist if:

1. You are allergic to any medicines, foods, dyes or preservatives.
2. You have any other health problems.
3. You are taking any other medicines.
4. You have diabetes.
5. You are being treated because you have a weak immune system.
6. You have poor circulation in your hands and feet.
7. Your nail is severely damaged or infected

- Taking other medicines

Nail varnish or artificial nails should not be used while using *Mycofine*. There are no known interactions with other medicines.

How to use *Mycofine*

- How much to use

Apply *Mycofine* evenly over the entire surface of each affected nail.

- When to use it

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

- How long to use it

It is important to carry on using *Mycofine* until the infection has cleared and healthy nails have grown back. This usually takes 6 months for finger nails and 9 to 12 months for toe nails. Your doctor will probably check how your treatment is progressing every 3 months or so.

- If you forget to use it

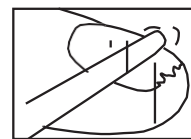
Do not worry if you forget to use *Mycofine* at the right time. When you remember, start using the product again, in the same way as before.

- If you use too much (overdose)

Accidental oral ingestion: Amorolfine Nail Lacquer is for topical use. In the event of accidental oral ingestion, an appropriate method of gastric emptying may be used.

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 the nail file provided.

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 files from your kit.

Step 2: Clean the nail



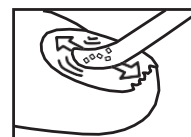
Use one of the swabs provided to clean the nail surface. Repeat steps 1 and 2 for each affected nail.

Step 3: Take some lacquer from the bottle



Dip one of the re-usable applicators into the bottle of nail lacquer. The lacquer must not be wiped off on the edge of the bottle before it is applied.

Step 4: Apply the lacquer



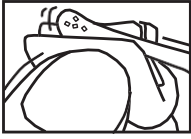
Apply the nail lacquer evenly over the entire surface of the nail. Repeat steps 3 and 4 for each affected nail.

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

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Step 5: Clean the applicator



The applicators provided are re-usable. However, it is important to clean them thoroughly after completing each treatment procedure, using the same 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 as it is inflammable.

While you are using it

- Things you must do
- Always use *Mycofine* exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- 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 may 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 *Mycofine* until the infection has cleared and healthy nails have grown back. This usually takes 6 months for finger nails and 9 to 12 months for toe nails
- Things you must not do
- Do not use nail files for infected nails on healthy nails.
- Do not use artificial nails during treatment with Amorolfine.
- Do not apply cosmetic nail varnish or other medication(s) on the nail(s) being treated.
- Do not give Amorolfine to anyone else to use, even if they have the same condition as you.
- Do not use Amorolfine to treat other complaints unless your doctor says to.

- Do not stop using *Mycofine* 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.

- Things to be careful of
- Avoid the lacquer coming into contact with the eyes, ears or mucous membranes (e.g. mouth and nostrils).
- If you get *Mycofine* in your eyes or ears wash out with water immediately and contact your doctor, pharmacist or nearest hospital straight away.
- Do not inhale.
- Do not apply to the nail bed as it may cause localised effects such as contact dermatitis.
- If you, or anyone else, accidentally swallows the lacquer contact your doctor, or nearest hospital straight away, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.
- Take care that Amorolfine does not come into contact with the skin

Side effects

Like all medicines, *Mycofine* can cause side effects, although not everybody gets them.

In addition to the beneficial effects of *Mycofine*, it is possible that unwanted effects will occur during treatment, even when it is used as directed.

- Rare side effects: Your nail may become discoloured, broken or brittle during treatment with Amorolfine nail lacquer. However, these reactions may also be linked to the nail infection itself.
- Very rare side effects: A burning sensation may occur in the area around the nail.

• Unknown frequency of occurrence: Allergic skin reaction (contact dermatitis).

- Itching or redness of the skin.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of *Mycofine*

- Storage
- Keep out of the reach and sight of children.
- Do not use *Mycofine* after the expiry date which is stated on the carton and bottle. 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.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

Product Description

- What it looks like

Mycofine is a clear, colourless to pale yellow solution.

It is available in 2.5 ml pack; 1 bottle packed with or without cleansing swabs, spatulas and / or nail files.

- Ingredients

- Active ingredient

Mycofine contains 50 mg/ml of the active substance amorolfine (equivalent to 55.74 mg/ml amorolfine hydrochloride).

- Inactive ingredients

Eudragit RL 100 (ammonio methacrylate copolymer A), triacetin, butyl acetate, ethyl acetate and ethanol (anhydrous).

- MAL Number

MAL18121005X

Manufacturer

Chanelle Medical Unlimited Company, Loughrea, Co. Galway, Ireland

Product Registration Holder

PAHANG PHARMACY Sdn Bhd (10826-K), Lot 5979 Jalan Teratai, 5½ Mile Off Jalan Meru, 41050 Klang, Selangor D.E., Malaysia

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04 April 2023

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