

Approved Patient Information Leaflet for Medicines for Human Use:

FUNGORYL 5 % Solution (Nail Lacquer)

SCHEDULING STATUS: **S1**

FUNGORYL 5 % Solution (Nail lacquer)

Amorolfine Hydrochloride

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

FUNGORYL 5 % is available without a health care provider 's prescription, for you to treat a mild illness, maintain your health. Nevertheless, you still need to use FUNGORYL 5 % carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share FUNGORYL 5 % with any other person.
- Ask your health care provider if you need more information or advice.

What is in this leaflet

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

1. What FUNGORYL 5 % is and what it is used for

FUNGORYL 5 % Solution (Nail lacquer)

Each Solution contains amorolfine hydrochloride equivalent to amorolfine 5 % w/v (50 mg /mL amorolfine base).

FUNGORYL 5 % is used to treat fungal infections of the nails.

FUNGORYL 5 % contains the 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.

Onychomycoses caused by dermatophytes, yeasts and moulds.

Only little experience is available in cases where the nail matrix was involved.

2. What you need to know before you take use FUNGORYL 5 %

Do not use FUNGORYL 5 %

- if you are hypersensitive to amorolfine or any of the other ingredients of FUNGORYL 5 % (listed in section 6)

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 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

Talk to your health care provider before using FUNGORYL 5 %.

- The lacquer should not be applied on the skin around the nail.

- Avoid the lacquer coming into contact with the eyes, ears or mucous membranes (e.g. mouth and nostrils).
- After applying FUNGORYL 5 %, an interval of at least 10 minutes should be allowed before application of any cosmetic nail lacquer. Before repeat application of FUNGORYL 5 %, the cosmetic nail lacquer should be removed carefully.
- Do not inhale.
- Wear impermeable gloves when using organic solvents to stop the nail lacquer from being removed.
- Do not use nail varnish or artificial nails during treatment with FUNGORYL 5 %.
- The nail lacquer is not affected by soap and water, so you may wash your hands and feet in the normal way.
- If you need to use chemicals such as white spirit or paint thinners, you must wear rubber gloves; otherwise the nail lacquer will dissolve.
- Due to the very low systemic absorption of amorolfine after using the nail lacquer a risk to the foetus appears to be negligible. (if applicable).

Children

Do not use FUNGORYL 5 % in children.

Other medicines and FUNGORYL 5 %

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

There are no known interactions with other medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your health care provider for advice before taking this medicine.

You should not use FUNGORYL 5 % and tell your health care provider if you are pregnant, planning to become pregnant or are breast-feeding. Your health care provider will then decide whether you should use FUNGORYL 5 %.

Ask your health care provider for advice before taking any medicine.

Driving and using machines

It is not always possible to predict to what extent FUNGORYL 5 % may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which FUNGORYL 5 % affects them.

3. How to use FUNGORYL 5 %

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

Always use FUNGORYL 5 % exactly as described in this leaflet or as your health care provider have told you. Check with your health care provider if you are not sure.

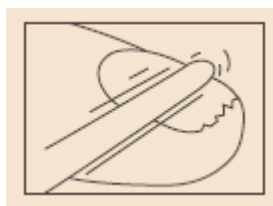
Duration of administration

Your health care provider will tell you how long your treatment with FUNGORYL 5 % will last. Do not stop treatment early. If you have the impression that the effect of FUNGORYL 5 % is too strong or too weak, tell your health care provider.

For Nail Lacquer Solutions

1. File the nail

File the affected nails, especially the diseased parts of the nail surface using the nail file provided.



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. To prevent the spread of infection, take care that no one else uses the files from your kit.

2. Clean the nail

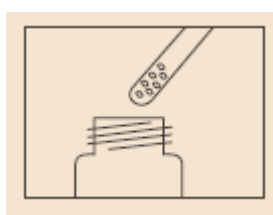
Using one of the swabs provided wipe the entire surface of the affected nail(s) and remove any previous coat of the nail lacquer.



3. Take some lacquer from the bottle

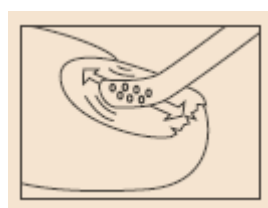
Dip the applicator into the bottle of nail lacquer.

The lacquer must not be wiped off the applicator on the edge of the bottle before it is applied.



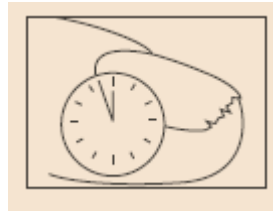
4. Apply the lacquer

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



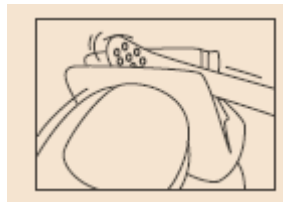
5. Allow to dry

Let the treated nail(s) dry for approximately three to five minutes.



6. Clean the applicator

The applicator provided is re-usable. However, it is important to clean it thoroughly after completing each treatment procedure, using the same swab you used for nail cleansing. Avoid touching newly treated nails with the swab.



7. Close the nail lacquer bottle tightly and throw away the used swab

The nail lacquer must be applied to the affected finger or toenails once or twice weekly.

- Every step of the treatment procedure is important. For a successful cure you must repeat each of the steps every time you treat your nails.
- These measures and precautions may appear fussy; however, they are indispensable because they speed up healing and prevent healthy nails from becoming infected.
- Cosmetic nail lacquer may be applied at least 10 minutes after FUNGORYL 5 % application.
- Remember: Successful treatment depends on your patience and perseverance.
- It is important to carry on using FUNGORYL 5 % 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.

If you get FUNGORYL 5 % in your eyes or ears

If you get FUNGORYL 5 % in your eyes or ears wash out with water immediately and contact your health care provider, or nearest hospital straight away.

If you accidentally swallow FUNGORYL 5 %

If you, or anyone else, accidentally swallows the lacquer contact your health care provider, or nearest hospital straight away.

If you forget to use FUNGORYL 5 %

Don't worry if you forget to use FUNGORYL 5 % at the right time. When you remember, start using the product again, in the same way as before.

If you take more FUNGORYL 5 % than you should

In the event of overdosage, consult your health care provider. If neither is available, contact the nearest hospital or poison centre.

If you stop using FUNGORYL 5 %

Do not stop using FUNGORYL 5 % before your health care provider tells you to or your infection could come back. If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

FUNGORYL 5 % can have side effects.

Not all side effects reported for FUNGORYL 5 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using FUNGORYL 5 %, please consult your health care provider for advice.

Less frequent side effects:

- Nail damages, nail discoloration, fragile or brittle nails.
- Skin burning sensation.

Side effects with frequency unknown:

- 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

If you notice any side effects not mentioned in this leaflet, please inform your health care provider.

Reporting of side effects

If you get side effects, talk to your health care provider. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of FUNGORYL 5 %.

5. How to store FUNGORYL 5 %

Store all medicines out of 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.
- 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.
- Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What FUNGORYL 5 % contains

- The active substance is amorolfine. FUNGORYL 5 % contains Each Solution contains amorolfine hydrochloride equivalent to amorolfine 5 % w/v (50 mg /mL amorolfine base)
- The other ingredients are ammonio methacrylate copolymer A, triacetin, butyl acetate, ethyl acetate and ethanol.

What FUNGORYL 5 % looks like and contents of the pack

FUNGORYL 5 % is supplied is available in sizes of 2,5 mL, 5 mL, 7,5 mL and 10 mL bottles. Each 2,5 mL and 5 mL pack consists of 1 bottle filled with FUNGORYL 5 % together with cleansing swabs, nail files and spatula integrated in the cap or separate spatulas. Each 7,5 mL and 10 mL pack consists of 2 bottles filled with FUNGORYL 5 % together with cleansing swabs, nail files, and spatula integrated in the cap or separate spatulas. Not all pack sizes may be marketed. Not all pack sizes may be marketed.

Holder of Certificate of Registration

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