PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

AMORTIVO 5 % nail lacquer

amorolfine (as hydrochloride)

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

AMORTIVO 5 % is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use AMORTIVO 5 % carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share AMORTIVO 5 % 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.

What is in this leaflet

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

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

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

AMORTIVO 5 % contains the active ingredient amorolfine, which belongs to a group of medicines known as antifungals. It kills a wide variety of fungi that can cause nail infections.

2. What you need to know before you use AMORTIVO 5 %

Do not use AMORTIVO 5 %:

- If you are hypersensitive (allergic) to amorolfine or any of the other ingredients of AMORTIVO 5 % (listed in section 6).
- If you are pregnant or breastfeeding.
- In children.

Warnings and precautions

Take special care with AMORTIVO 5 %:

- Do not apply AMORTIVO 5 % on the skin around the nail.
- Avoid contact of the lacquer with eyes, ears and mucous membranes.
- Artificial nails should not be used while using AMORTIVO 5 %.
- Cosmetic nail varnish can be used, but you should wait at least 10 minutes after applying AMORTIVO 5 % before painting your nails. The nail varnish should be carefully removed before repeat application of AMORTIVO 5 %.
- If you need to use chemicals such as white spirit or paint thinners, you must wear rubber gloves, otherwise the nail lacquer will dissolve.
- AMORTIVO 5 % can cause a serious allergic reaction. If this happens, immediately remove AMORTIVO 5 % with a nail varnish remover and seek medical advice. Do not reapply AMORTIVO 5 %.

Children and adolescents

Children should not be treated with AMORTIVO 5 %.

Other medicines and AMORTIVO 5 %

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

There are no known interaction with other medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using AMORTIVO 5 %.

Do not use AMORTIVO 5 % if you are pregnant or breastfeeding.

Driving and using machines

AMORTIVO 5 % is unlikely to affect your ability to drive a vehicle and use machines.

3. How to use AMORTIVO 5 %

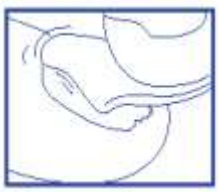
Always use AMORTIVO 5 % exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Apply AMORTIVO 5 % nail lacquer to affected finger- or toenails once or twice weekly.

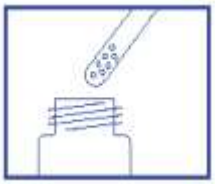


1. File the affected nails, especially the diseased parts of the nail surface, to eliminate as much as possible of the diseased nail and the fungus affecting it.

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.



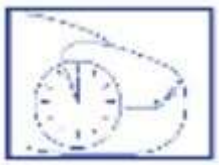
2. Using one of the pre-soaked pads provided, wipe the entire surface of the affected nail(s). Take care to remove any previous coat of medicated nail lacquer.



3. Dip the applicator into the bottle of medicated nail lacquer. The lacquer must not be wiped off the applicator on the edge of the bottle before it is applied.



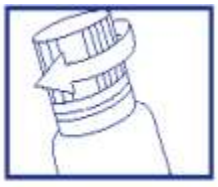
4. Apply the nail lacquer evenly over the entire surface of the nail. Repeat steps 3 and 4 for each affected nail.



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



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



7. Close the nail lacquer bottle tightly and throw away the used pad. The medicated nail lacquer provided 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 and paint thinner, you must wear rubber gloves, otherwise the nail lacquer will dissolve.

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.
Remember: Successful treatment depends on your patience and perseverance.

It is important to carry on using AMORTIVO 5 % 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.

If you swallow AMORTIVO 5 %

If you accidentally swallow the lacquer, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use AMORTIVO 5 %

Don’t worry if you have forgotten to apply AMORTIVO % at the right time. When you remember, start using it again in the same way as before.

4. Possible side effects

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

If any of the following happens, stop using AMORTIVO 5 **%** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your 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 allergic reaction to AMORTIVO 5 %. You may need urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Nail damages, nail discolouration, fragile and brittle nails.

Less frequent:

- Burning sensation of the skin.

Side effects with an unknown frequency:

- Systemic (i.e., affecting the whole body) hypersensitivity (allergic) reaction, with symptoms such as swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing (see *"If any of the following happens, stop using AMORTIVO 5 %*" above).
- Allergic skin reaction, also known as contact dermatitis.
- Redness of the skin or mucous membranes (erythema).
- Itchy skin (pruritis).
- Hives, an outbreak of swollen, pale red bumps or plaques (wheals) on the skin (urticaria).
- Skin blisters.

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

Reporting of side effects

If you get side effects, talk to doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “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 AMORTIVO 5 %.

5. How to store AMORTIVO 5 %

- Store at or below 25 °C.
- Protect from heat.
- Keep the bottle upright and tightly closed.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What AMORTIVO 5 % contains

The active substance in AMORTIVO 5 % is amorolfine (as hydrochloride).

The other ingredients are *n*-butyl acetate, ethyl acetate, anhydrous ethanol (55,4 %), Eudragit RL 100 (ammonio methacrylate copolymer type A) and triacetin.

What AMORTIVO 5 % looks like and contents of the pack

AMORTIVO 5 % is a clear, colourless to pale yellow solution.

2,5 mL solution filled in amber glass (Type I or Type III) bottle with an HDPE cap with PTFE liner and tamper-evident ring.

Supplied with 30 swabs (alcohol wipes), 30 nail files and 10 LDPE applicators.

Holder of Certificate of Registration and Manufacturer

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