Package leaflet: Information for the user

Care Antifungal 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 you feel worse after 3 months.

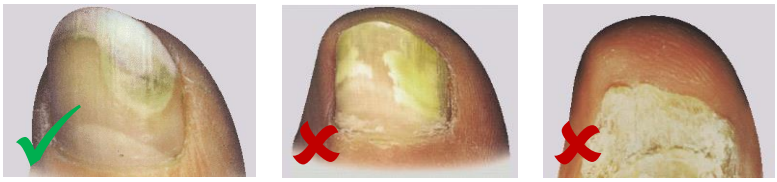
What is in this leaflet

1. What Care Antifungal 5%w/v Medicated Nail Lacquer is and what it is used for
2. What you need to know before you use Care Antifungal 5%w/v Medicated Nail Lacquer
3. How to use Care Antifungal 5%w/v Medicated Nail Lacquer
4. Possible side effects
5. How to store Care Antifungal 5%w/v Medicated Nail Lacquer
6. Contents of the pack and other information
7. General advice for people with fungal nail infections

1. What Care Antifungal 5%w/v Medicated Nail Lacquer is and what it is used for

- Care Antifungal 5%w/v Medicated Nail Lacquer contains the active substance amorolfine. This belongs to a group of medicines called antifungals.
- Care Antifungal 5%w/v Medicated Nail Lacquer is used to treat mild fungal nail infections in adults aged 18 years and over.
  It should only be used if:
  - you have 1 or 2 nails affected
  - the upper half or sides of the nail are affected (see picture 1).

  Talk to your doctor if the infection appears to be more like pictures 2 or 3.



Mild ✓ Moderate × Severe ×

Amorolfine kills a wide variety of fungi that can cause nail infections. Fungal nail infections can look very different, your nails could be discoloured (white, yellow or brown), thick or brittle.

2. What you need to know before you use Care Antifungal 5%w/v Medicated Nail Lacquer

DO NOT use Care Antifungal 5%w/v Medicated Nail Lacquer if:
- you are allergic to amorolfine or any of the other ingredients of this medicine (listed in section 6)

- your nail does not look similar to picture 1 above
- your nail is moderately or severely damaged or infected (see pictures 2 and 3 above)
- you have poor blood circulation in your hands or feet
- you have pain or swelling around the nail
- you have more than 2 infected nails in total
- you have a weak immune system
- you are under the age of 18
- you have diabetes
- you have dark stripes running down the nail

Do not use this medicine if any of the above apply to you. If you are not sure, tell your doctor of pharmacist before using amorolfine.

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

Do not apply Care Antifungal 5%w/v Medicated Nail Lacquer on the skin around the nail.

Other nail products and Care Antifungal 5%w/v Medicated Nail Lacquer
Artificial nails should not be used while using Care Antifungal 5%w/v Medicated Nail Lacquer. Cosmetic nail varnish can be used, but you should wait at least 10 minutes after applying Care Antifungal 5%w/v Medicated Nail Lacquer before painting your nails. The nail varnish should be carefully removed before repeat application of Care Antifungal 5%w/v Medicated Nail Lacquer.

Other medicines and Care Antifungal 5%w/v Medicated Nail Lacquer
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. You can normally use this medicine when you are taking other medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

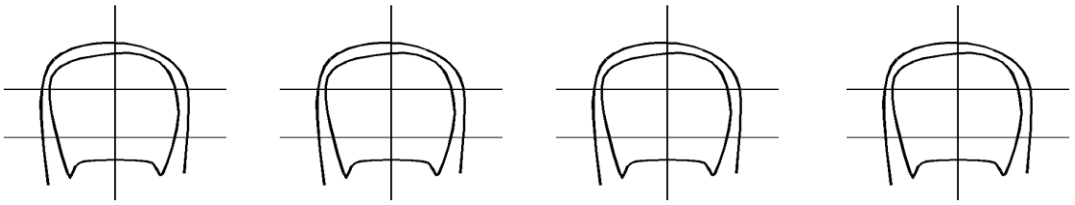
Care Antifungal 5%w/v Medicated Nail Lacquer contains alcohol (ethanol)
This medicine contains 0.61ml alcohol (ethanol) in each ml. It may cause burning sensation on damaged skin.

3. How to use Care Antifungal 5%w/v Medicated Nail Lacquer

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

Keeping a record
Before you start using the medicine, you should keep a record of how your nail looks:
- Shade the area affected by the infection in the 'Before Treatment' diagram below.
- If you have 2 nails affected, just do this for your worst nail.
- Every 3 months, shade the area affected in the next diagram.
- Do this until the infected nail has completely grown out.

This will help you remember how your nail looked so you can see your progress.



Before treatment | Three Months | Six Months | Nine Months

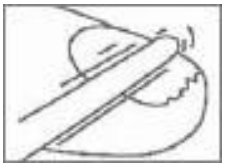
Safe use of Care Antifungal 5%w/v Medicated Nail Lacquer

- If you get the medicine in your eyes or ears, wash it out with water and talk to your doctor or pharmacist or go to the nearest hospital straight away.
- Do not let the medicine come into contact with your mouth or nostrils (or other 'mucous membranes').
- Do not inhale the medicine.
- Do not let anyone else use the files from your kit - this will stop the spread of infection.
- If you need to use chemicals such as paint thinners or white spirit when you have applied the medicine to your fingernails, wear rubber or other waterproof (impermeable) gloves. This will protect the medicine on your nails.

How to use - first use

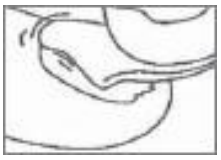
Step 1: Prepare your nail

- Protect your healthy nails so that you don't spread the infection.
- Use a new file.
- Gently file down the infected areas of your nail - including the nail surface.
- **Do not use the same nail file** for infected nails and healthy nails - this could spread the infection.



Step 2: Clean your nail

- Use one of the swabs provided (or nail varnish remover)
- Clean the nail surface.
- Do not throw the swab away - you will need it later to clean the applicator.



Step 3: Treat the nail

- Dip the applicator into the bottle of nail lacquer.
- **Do not wipe the lacquer off** on the edge of the bottle before it is applied.
- Apply the lacquer evenly over the entire surface of the nail.
- Allow it to dry - let the treated nail(s) dry for about 3 minutes. When the lacquer is dry it is not affected by soap and water. You can wash your hands or feet as normal. Wait at least 10 minutes before applying cosmetic nail varnish.



Step 4: Clean the applicator

- You can use the applicator more than once.
- It is important to clean it after each use – so you do not spread the infection.
- Use the same swab you used for cleaning your nails.
- Do not touch the newly treated nails with the swab.
- Close the nail lacquer bottle tightly.
- **Throw the swab away carefully as it will set on fire easily.**
- It is important to carry on using the nail lacquer every week 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 the nail is still infected after this time you should see a doctor.
- If you do not continue using the nail lacquer every week the treatment may not work as expected and the fungus could also become resistant to the nail lacquer.

How to use - after first use
Each infected nail should be treated once a week.
- Before using the lacquer again, remove the old lacquer and any nail varnish from your nails using a swab.
- File down the nails again if needed.
- Re-apply the lacquer as described in Step 3 above.
- Clean the applicator as described in Step 4 above.

How long to use
- You need to use the medicine once a week 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.
- You will see a healthy nail growing as the infected nail grows out.
- Nails grow slowly so it may take 2 or 3 months before you start to see an improvement.
- After every 3 months of treatment:
  - If the infection has improved, continue the treatment.
  - If the infection is the same or worse talk to your doctor or pharmacist. Take this leaflet with you.

The images below show two examples of a nail at different time points: before and after successful treatment.


Before treatment


After treatment

If you accidentally swallow Care Antifungal 5%w/v Medicated Nail Lacquer
If you, or anyone else, accidentally swallows the medicine, talk to your doctor or pharmacist or go to the nearest hospital straight away.

If you forget to use Care Antifungal 5%w/v Medicated Nail Lacquer
Do not worry if you forget to use the lacquer exactly a week after the last time. When you remember, use the medicine again, in the same way as before. You could use a diary to remind you. Do not use a double dose to make up for a forgotten dose.

If you stop using Care Antifungal 5%w/v Medicated Nail Lacquer
Do not stop using the medicine until your nail improves, as the infection could come back. This generally takes 6 months for fingernails and 9-12 months for toenails. The images in 'How long to use' can help you understand what you are looking for.
.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may happen with this medicine:

Rare: may affect up to 1 in 1,000 people
- Nail damages, nail discoloured, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Care Antifungal 5%w/v Medicated Nail Lacquer

- Keep this medicine out of the sight and 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.
- Store below 30 °C. Protect from heat. Keep the bottle tightly closed and upright.

This product is flammable! Keep the solution away from fire and flames!

- 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.

6. Contents of the pack and other information

What Care Antifungal 5%w/v Medicated Nail Lacquer contains
What < Invented Name > contains:
-The **active** ingredient is amorolfine. Each milliliter contains 55.74 mg amorolfine hydrochloride (equivalent to 50 mg amorolfine).
-The **other** excipients are Eudragit RL 100 (ammonio methacrylate copolymer A), triacetin, butyl acetate, ethyl acetate and ethanol (anhydrous).

What Care Antifungal 5%w/v Medicated Nail Lacquer looks like and contents of the pack
Care Antifungal 5%w/v Medicated Nail Lacquer is a clear, colourless to pale yellow solution. It is available in

2.5 ml, 3 ml and a 5 ml packs; 1 bottle packed with or without cleansing swabs, spatulas and / or nail files.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
The marketing authorisation holder is
Thornton & Ross Limited, Linthwaite, Huddersfield, HD7 5QH, UK
The manufacturer is Chanelle Medical Unlimited Company, Dublin Road, Loughrea, H62 FH90, Ireland

This leaflet was last revised in December 2022.

7. General advice for people with fungal nail infections

You can reduce your risk of developing a fungal nail infection by:

- keeping your hands and feet clean and dry
- wearing well-fitting shoes made of natural materials and clean cotton socks - these will allow your feet to 'breathe'
- clipping your nails to keep them short - don't share clippers or scissors with other people
- not sharing towels and socks with other people - ensure you wash your towels regularly
- not walking around barefoot in public pools, showers, or locker rooms - special shower shoes are available to protect your feet,
- replacing old footwear that could be contaminated with fungi
- treating athlete's foot as soon as possible to stop the infection spreading to your nails.

Nail salon equipment can sometimes be the source of fungal nail infections. If you regularly visit a salon, make sure any equipment used is properly sterilised between uses.