

Schollmed Once Weekly Fungal Nail Treatment 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.
- Know this leaflet. You must read it again if your doctor or pharmacist gives you 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.

In this leaflet:

1. What Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer is and what it is used for
2. What you need to know before you use Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer
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1. What Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer is and what it is used for:

Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer is used to treat mild fungal nail infections affecting up to 2 nails and affecting the upper half or sides of the nail (as shown in the first picture below). If the infection appears to be more like pictures 2 or 3, you should consult your doctor. This medicine is indicated for use in adults aged 18 years and over. The active substance is amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals. Amorolfine kills a wide variety of fungi that can cause nail infections. A fungal nail infection is likely to result in discoloured (white, yellow or brown), thick or brittle nails, although their appearance can vary considerably as the following pictures show:



2. What you need to know before you use Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer

Do not use Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer if

- your nail does not look similar to picture 1 above
- you are allergic to amorolfine or any of the ingredients of this medicine (listed in section 4)
- you are pregnant, might become pregnant or are breastfeeding
- you have pain or swelling around the nail
- you have poor blood circulation in your hands or feet
- you have more than 2 infected nails in total
- you are under the age of 18
- 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, talk to your doctor or pharmacist before using this medicine.

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:

- Do not apply on the skin around the nail. This medicine contains 55.4% w/v alcohol (ethanol) that may cause burning sensation on damaged skin.
- You have difficulty breathing
- Your face, lips, tongue or throat swell

Other medicines and Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This includes medicines obtained without a prescription, and herbal medicines. You can normally use the nail lacquer whilst you are taking other medicines.

Using other nail products

Artificial nails should not be used while using this medicine. Cosmetic nail varnish can be used, but you should wait at least 10 minutes after applying this product before painting your nails. The nail varnish should be carefully removed before repeat application of this product.

Pregnancy and breast-feeding

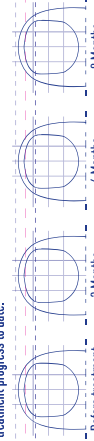
Do not use Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer if you are pregnant, might become pregnant or are breastfeeding.

3. How to use Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer

Always use this medicine 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.

Before Commencing Treatment:

In the diagram below, shade the area affected by the fungal nail infection in the 'Before treatment' diagram below. This will help you in remembering how the nail looked originally when your treatment is reviewed. Every three months, shade the area now affected until the infected nail has completely grown out. If more than one nail is affected, select the worst affected nail for this exercise. Take this leaflet to the pharmacist or podiatrist when treatment is being reviewed to inform them of treatment progress to date.



How long to use. You need to use this medicine once a week 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. • 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. It is important to carry on using the nail lacquer until the infection has cleared and healthy nails have grown back.

Safe use of this medicine: If you get this 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 in contact with your mouth or nostrils (or other mucous membranes). Do not inhale the medicine. Do not let anyone else use the files from this kit as this will stop the spread of infection. If you need to use nail clippers or a nail brush, wash them with soap and water. If you have applied the medicine to your fingernails, wear rubber or other waterproof (impervious) gloves. This will protect the medicine on your nails.

The following steps should be followed carefully for each affected nail:

Step 1: File the nail

Dip one of the re-usable applicators into the bottle of nail lacquer. The lacquer must not be wiped off the edge of the bottle before it is applied. Protect any healthy nail while you are doing this so that you don't spread the infection. **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 (or nail varnish remover) to clean the nail surface. Do not throw the swab away as you will need it later to clean the applicator. Repeat steps 1 and 2 for each affected nail.

Step 3: Apply the lacquer

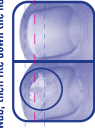
Dip one of the re-usable applicators into the bottle of nail lacquer. The lacquer must not be wiped off the edge of the bottle before it is applied. Apply the lacquer evenly over the entire surface of the nail. Repeat this step for each affected nail. Let the treated nail(s) dry for approximately 3 minutes. 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

The applicators provided are re-usable (can be used more than once). However, it is important to clean them thoroughly after completing each treatment procedure so you don't spread the infection. Use the same swab you used for nail cleansing. Avoid touching 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 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. You will see a healthy nail growing as the infected nail grows out.
- 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 nail lacquer again, remove the old lacquer and any nail varnish from your nails using a swab, then file down the nails again, if necessary. Re-apply the lacquer as described above.



Before Treatment

If you accidentally swallow Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer
If you, or anyone else, accidentally swallows the lacquer contact your doctor, pharmacist or nearest hospital straight away.

If you forget to use Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer
Do not worry if you forget to use the lacquer at the right time. When you remember, start using the product again, in the same way as before.

If you stop using this Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer
Do not stop using this medicine before your doctor tells you to or your infection could come back.

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.

Rare: may affect up to 1 in 1,000 people: Skin burning sensation.

Frequency Not known: frequency cannot be estimated from the available data: Systemic allergic reaction (a serious reaction that can be associated with the swelling of the face, lips, tongue or throat, difficulty breathing and/or a severe skin rash.

Redness, itching, hives, blisters and allergic skin reaction (contact dermatitis)

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for 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 Schollmed Once Weekly Fungal Nail Treatment 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 bottle. 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Waste material contaminated with medicines should also not be disposed of via wastewater. These measures will help protect the environment.

6. Contents of the pack and other information

What Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer contains

The active substance is amorolfine. 1 ml solution contains 55.4 mg amorolfine hydrochloride (equivalent to 50 mg amorolfine).

The other ingredients are Ethylhexyl Di, 100, triacetate, butyl acetate, ethyl acetate and ethanol.

What Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer looks like and contents of the pack

The lacquer is a clear, colourless to pale yellow solution, available in a glass bottle of 2.5 ml. The bottle is made of amber glass (type I or type III) bottle with a HDPE cap. PTFE liner and tamper evident ring. Each pack consists of 1 bottle and cleansing swabs, spatulas and nail files.

Marketing Authorisation Holder and Manufacturer

Chanelle Medicine Unlimited Company, Dublin Road, Loughrea, Co. Galway, Ireland

This leaflet was last revised in May 2025.

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