

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

Amorolfine (as Amorolfine Hydrochloride)

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.

This medicine is available without prescription. However, you still need to use Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer carefully to get the best results from it.

- 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

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
How to use Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer
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4. Contents of the pack and other information

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 fungal 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.
- The active substance Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer is amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals.
- Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer 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 do 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 you are allergic (hypersensitive) to the active ingredient (amorolfine) or any of the other ingredients of Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer (see section 6 for other ingredients)
- If you are under the age of 18

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 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 doctor or pharmacist before using Amorolfine,

- if you suffer from diabetes
- if you are being treated because you have a weak immune system
- if you have poor circulation in your hands and feet
- if your nail is severely damaged or infected

If you get Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer in your eyes or ears wash it out with water immediately and contact your doctor, pharmacist or nearest hospital straight away.

Avoid the lacquer coming into contact with mucous membranes (e.g. mouth and nostrils). Do not breathe it in.

Wear impermeable gloves when using organic solvents to stop the nail lacquer from being removed. Do not use cosmetic nail lacquer or artificial nails during treatment with amorolfine.

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

You can use the nail lacquer whilst you are taking other medicines.

Using other nail products

Nail varnish or artificial nails should not be used while using 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.

Pregnancy and breast-feeding

You should not use Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer 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 Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer.

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

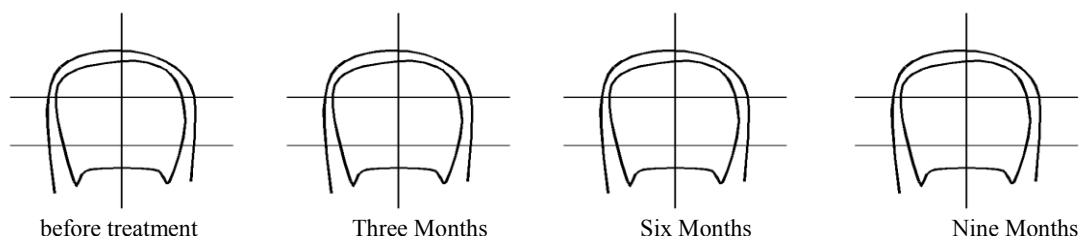
3. How to use Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer

Always use Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and the Elderly

Before Commencing Treatment

In the diagram below, shade the area affected by the fungal nail infection. 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.



Instructions for use

- Treat your infected nails as described below. **NAILS SHOULD BE TREATED ONCE A WEEK.**
- Once weekly application should continue for 6 months for finger nails and 9 to 12 months for toe nails. A review of the treatment is recommended at intervals of approximately three months.
- Nails grow slowly so it may take 2 or 3 months before you start to see an improvement.
- It is important to carry on using the nail lacquer until the infection has cleared and healthy nails have grown back.
- The following steps should be followed carefully for each affected nail:

Step 1: File the nail

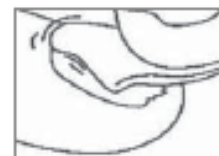
Before the first application, file down the infected areas of nail, including the nail surface, as much as possible using the nail file provided.

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 (or nail varnish remover) to clean the nail surface. 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.



Step 4: 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.



- 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 can 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 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. You will see a healthy nail growing as the diseased nail grows out.



Before treatment



After 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 Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer Do not stop using Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer 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.

4. Possible side effects

Like all medicines, Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer can cause side effects, although not everybody gets them.

Rare side effects (may affect up to 1 in 1000 people)

Your nail may become discoloured, broken or brittle.

Very rare side effects (may affect up to 1 in 10,000 people)

A burning sensation may occur in the area around the nail.

Frequency not known (frequency cannot be estimated from the available data)

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 HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2, Ireland. Tel: +353 1 6764971; Fax: +353 1 6762517. Website; www.hpra.ie; email: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <invented name>

- Keep out of the reach and sight of children
- Do not use Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer 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!

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.

6. Contents of the pack and other information

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

1 ml of Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer contains 55.74 mg amorolfine hydrochloride (equivalent to 50mg amorolfine). The other ingredients are Eudragit RL 100 (ammonio methacrylate copolymer A), triacetin, butyl acetate, ethyl acetate and ethanol (anhydrous).

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

Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer is a clear, colourless to pale yellow solution. It is available in 2.5 ml and 3 ml packs; 1 bottle packed with cleansing swabs, spatulas and nail files. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

PA Holder: Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. Manufacturer: Channelle Medical, Dublin Road, Loughrea, Co. Galway.

This leaflet was last reviewed in: April 2018