#### **Consumer Medicine Information**

#### What is in this leaflet

This leaflet answers some common questions about Chemists' Own Amer-Fine nail lacquer.

It does not contain all of the available information. It does not take the place of talking to your doctor, pharmacist or podiatrist.

# If you have any concerns about using this medicine, talk to your doctor, pharmacist or podiatrist.

Keep this leaflet with your medicine. You may need to read it again.

## What Chemists' Own Amer-Fine is used for

Chemists' Own Amer-Fine contains the active ingredient amorolfine. It is used to treat fungal infections of the nails.

Amorolfine belongs to a group of medicines called anti-fungal drugs. These medicines work by killing a wide variety of fungi that can cause nail infections.

This medicine is available from a pharmacy. A doctor's prescription is not required.

Amer-Fine treatment alone is not suitable for use in severe infections where the lunula (crescent-shaped area at the base of the nail) is affected. In this case you should talk to your doctor, pharmacist or podiatrist.

Because fungal nail infections are hard to treat, treatment may be required for 6-12 months or longer and a full cure cannot be expected in all cases. After 6 months of treatment, improvement can be expected in 70% to 80% of people, with full cure expected in approximately one in three people.

## Before you use Chemists' Own Amer-Fine

#### When you must not use it

Do not use Chemists' Own Amer-Fine if you are allergic to medicines containing amorolfine or any of the ingredients listed at the end of this leaflet.

# Do not use this medicine if you are pregnant or breastfeeding or intend to become pregnant or breastfeed.

The safety of this medicine in pregnancy and breastfeeding has not been established.

Do not use this medicine if the expiry date printed on the pack has passed.

Do not use this medicine if the packaging is torn or shows signs of tampering.

Do not use this medicine in children under 12 years of age.

The safety and effectiveness of this medicine have not been established in children.

#### Before you start to use it

Tell your doctor, pharmacist or podiatrist if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor, pharmacist or podiatrist if you are taking any other medicines.

If you have not told your doctor, pharmacist or podiatrist about any of the above, tell them before you start using Chemists' Own Amer-Fine.

#### How to use Chemists' Own Amer-Fine

Do not swallow Chemists' Own Amer-Fine. This medicine is for external use only. Apply only to finger nails and toe nails, avoid the surrounding skin.

Follow all directions given to you by your doctor, pharmacist or podiatrist carefully.

How to apply Chemists' Own Amer-Fine

### Follow these instructions each time the lacquer is used

- 1. Place everything you need for the treatment within easy reach:
  - Chemists' Own Amer-Fine nail lacquer
  - nail file
  - cleaning pad
  - reusable spatula

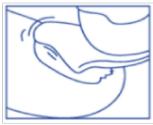
#### First application of Chemists' Own Amer-Fine nail lacquer:

 Before painting with Chemists' Own Amer-Fine nail lacquer, file down the infected areas of the nails (particularly the nail surfaces) as thoroughly as possible using the nail file.
CAUTION: Nail files used on an

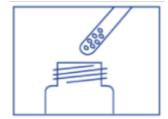
**CAUTION:** Nail files used on an infected nail must not be used on healthy nails.



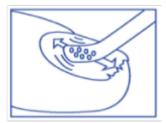
Clean the surfaces of all infected nails with a cleaning pad.



 Dip one of the reusable spatulas into the lacquer. Do not wipe it on the neck of the bottle. Note: the spatula provides a measured dose of Chemists' Own Amer-Fine.



 Using the spatula, paint Chemists' Own Amer-Fine nail lacquer over the entire surface of the infected nail.



- 6. Repeat steps 4 and 5 for each infected
- 7. Close the bottle tightly immediately after painting the infected nails.



8. Allow time for the nails to dry (3 to 5 minutes).



 When you have finished treating all of your infected nails, clean the spatula and the neck of the bottle with an unused cleaning pad.



 Discard used cleaning pads and nail files. Stow spatula and nail lacquer for next treatment.

#### Subsequent applications of Chemists' Own Amer-Fine nail lacquer:

File the infected areas of the nails using the nail file as required to remove any remaining lacquer, ensure that you do not over-file to avoid damage to the nails and surrounding area. Repeat steps 3-10.

How often to apply Chemists' Own Amer-Fine

Paint Chemists' Own Amer-Fine once or twice weekly on the infected fingernails or toenails or as otherwise directed by your doctor, pharmacist or podiatrist.

If you forgot to paint on the Chemists' Own Amer-Fine nail lacquer, use it as soon as you remember. Then go back to using it as you would normally.

If you are not sure what to do, ask your doctor, pharmacist or podiatrist.

# How long Chemists' Own Amer-Fine should be used

Treatment should be continued until infected nails are completely cured and regrown. Usually, treatment of fungal infections of the nails takes around six months for the fingernails and nine to twelve months for the toenails.

Don't be discouraged if after several weeks of therapy no improvement is visible. A healthy nail only grows by approximately 2mm per month.

It is recommended that you check with your doctor, pharmacist or podiatrist on the progression of your treatment every 3 months or so.

In case of accidental swallowing

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have swallowed Chemists' Own Amer-Fine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

# While you are using Chemists' Own Amer-Fine

#### Things you must do

Before starting any new medicine, tell your doctor, pharmacist or podiatrist that you are using Chemists' Own Amer-Fine.

Wear gloves to protect the coat of nail lacquer on your fingernails if you work with solvents (e.g. paint thinners, turpentine substitute, petrol, paraffin etc.).

If you become pregnant while using this medicine, tell your doctor.

Things you must not do

Do not use nail files for infected nails on healthy nails.

Do not use artificial nails during treatment with this medicine.

Do not apply cosmetic nail varnish or other medication(s) on the nail(s) being treated.

Do not use this medicine to treat any other conditions unless your doctor tells you to.

#### Things to be careful of

Take care that this medicine does not come into contact with the skin.

#### Side effects

Tell your doctor, pharmacist or podiatrist as soon as possible if you do not feel well while you are using Chemists' Own Amer-Fine

This medicine helps most people with fungal infections of the nails, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor, pharmacist or podiatrist to answer any questions you may have.

Tell your doctor, pharmacist or podiatrist if you notice any of the following and they worry you:

- burning feeling in the area surrounding the treated nail(s). This is usually mild and shortlasting
- itching or redness of the skin
- rare cases of nail disorder (nail discolouration, brittle or broken nails) have been reported during treatment with amorolfine nail lacquer. However these reactions may also be linked to the nail infection itself.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using Chemists' Own Amer-Fine

#### Storage

# Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep this medicine in a cool dry place where the temperature stays below 30°C.

Do not store Chemists' Own Amer-Fine or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

#### Disposal

If you stop using this medicine, or the expiry date has passed, ask your pharmacist what to do with any that is left over.

#### Product description

#### What it looks like

Chemists' Own Amer-Fine nail lacquer comes in one strength, 5% amorolfine (50 mg/mL) in an amber glass bottle.

Each pack contains:

- 1 bottle of 5 mL nail lacquer
- 10 spatulas
- 60 cleaning pads
- 30 nail files.

For information on how to obtain additional nail files or cleaning pads, please go to the Chemists' Own website,

www.chemistsown.com.au.

#### Ingredients

The active ingredient in Chemists' Own Amer-Fine is amorolfine. Each bottle contains 50 mg/mL of amorolfine base.

The nail lacquer also contains:

- ammonio methacrylate copolymer (type A)
- · triacetin
- butyl acetate
- ethyl acetate
- · absolute ethanol

#### Manufacturer/Supplier

#### Chemists' Own®

Arrow Pharma Pty Ltd 15 - 17 Chapel Street Cremorne VIC 3121

#### www.chemistsown.com.au

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