Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- 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.

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

What Loceryl is and what it is used for
Loceryl is used to treat fungal infections of the nails.

- Loceryl contains the active ingredient amorolfine (as the hydrochloride), which belongs to a group of medicines known as antifungals. It is a widely varying type of drug that can cause nail infections.

1. What Loceryl is and what it is used for

2. What you need to know before you use Loceryl

- Do not use Loceryl if you are:
  - Allergic (hypersensitive) to amorolfine or any of the other ingredients of Loceryl (see section 6 for other ingredients).

3. How to use Loceryl

- Before using Loceryl always read the instructions on the leaflet and the bottle.
- Use one of the swabs provided with the package and seek medical advice. The product must not be reapplied.
- Close the nail lacquer bottle tightly. Dispose of the swab carefully as it is inflammable.
- The applicator provided is reusable. However, it is important to carry on using Loceryl 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.
- Your doctor will probably check how your treatment is progressing every 3 months or so.
- If you get Loceryl in your eyes or ears:
  - If you get Loceryl in your eyes or ears, wash out with water immediately and contact your doctor, pharmacist or nearest hospital straight away.
- If you accidentally swallow Loceryl:
  - If you, or anyone else, accidentally swallows the lacquer contact your doctor, pharmacist or nearest hospital straight away.
- If you forget to use Loceryl:
  - Don’t worry if you forget to use Loceryl at the right time. When you remember, start using the product again, in the same way as before.
- If you stop using Loceryl:
  - Don’t stop using Loceryl before your doctor tells you to or your infection could come back.

4. Possible side effects

- 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
  - Talk to your doctor or pharmacist before using Loceryl.
  - The lacquer should not be applied on the skin around the nail.
  - Avoid the lacquer coming into contact with the eyes, ears or mucous membranes (e.g. mouth and nostrils).
  - Do not inhale.
  - Wear impermeable gloves when using organic solvents to stop the nail lacquer from being removed.

Using other medicines
- There are no known interactions with other medicines.

Using other nail products
- Artificial nails should not be used while using Loceryl.

Cosmetic nail varnish can be used, but you should wait at least 10 minutes after applying Loceryl before painting your nails.

The nail varnish should be carefully removed before repeat application of Loceryl.

Pregnancy and breast-feeding
- You should not use Loceryl 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 Loceryl. Ask your doctor or pharmacist for advice before taking any medicine.

3. How to use Loceryl

- Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Loceryl should be applied to the affected finger or toe nails once or twice a week as directed by your doctor.

Instructions for use

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 nail on healthy nails, otherwise you may spread the infection.

To prevent the spread of infection take care that no one else uses the file from your kit.

Step 2. Clean the nail
Use one of the swabs provided to clean the nail surface. Repeat steps 1 and 2 for each affected nail.

Step 3. Take some lacquer from the bottle
Drop the applicator into the bottle of nail lacquer. The lacquer must not be wiped off on the edge of the bottle before it is applied.

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

Step 5. Allow to dry
Let the treated nail(s) dry for approximately 3 minutes. Wait at least 10 minutes before applying coats of nail varnish.

Step 6. Clean the applicator
The applicator provided is re-usable. However, it is important to clean it thoroughly after completing each treatment, 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 Loceryl always read the instructions on the leaflet and the bottle.
• 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.
• Keep the pack away from heat (store below 30°C) and keep the bottle tightly closed after use.
• Do not use this medicine if you are: pregnant, planning to become pregnant or breast-feeding, or breast feeding.
• Do not use nail files used for infected nails on healthy ones.
• Keep this medicine out of the sight and reach of children.
• Do not use nail files used for infected nails on healthy nails, otherwise you may spread the infection.
• Do not use other medicines on the nail area.

5. How to store Loceryl

6. Contents of the pack and other information

What Loceryl contains
- The active substance is amorolfine. Loceryl contains 50 mg/ml (5%) of amorolfine (equivalent to 6.4% amorolfine hydrochloride).
- The other ingredients are: amononmethyloxirane copolymer A, triacetin, butyl acetate, ethyl acetate and ethanol.

What Loceryl looks like and contents of the pack
- The pack is available in sizes of 2.5 ml, 5 ml, 7.5 ml and 10 ml bottles.
- Each 2.5 ml and 5 ml pack consists of 1 bottle filled with Loceryl nail lacquer together with cleaning swabs, nail file and squadula integrated in the cap or separate swatches.
- Each 7.5 ml and 10 ml pack consists of 2 bottles filled with Loceryl nail lacquer together with cleaning swabs, nail files and squadula integrated in the cap or separate swatches.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
- Marketing Authorisation Holder is Galderma UK Ltd, Meriden House, 69-71 Clarendon Road, Watford, Herts, WD17 1SD, United Kingdom. (PL 10590/0042)
- Manufacturer: Laboratorios Galderma, 0 Montesa, 74504 Allo-de-Chalais, France.
- You can get more information on Loceryl Nail Lacquer from your doctor or pharmacist.

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