

Public Assessment Report

Decentralised Procedure

Amorolfine 5% W/V Medicated Nail Lacquer
Amorolfine Hydrochloride 5% W/V Nail Lacquer
Tinecur 5% W/V Medicated Nail Lacquer
Amorstad 5% W/V Medicated Nail Lacquer

UK/H/4506-4510&4512-4516/001/DC

UK licence nos: PL 13931/0073
PL 13931/0075-83

Applicant: Chanelle Medical

LAY SUMMARY

On 20 July 2011, the Medicine and Healthcare products Regulatory Agency (MHRA) granted Chanelle Medical Marketing Authorisations (licences) for the medicinal product Amorolfine hydrochloride 5% w/v Nail Lacquer. The product is licensed under the following names but will be referred to as Amorolfine 5% w/v Nail Lacquer throughout the remainder of this report:

PL Number	Procedure Number	Product Name	Legal Status
PL 13931/0075	UK/H/4510/001/DC	Amorolfine 5% w/v Medicated Nail Lacquer	POM
PL 13931/0077	UK/H/4507001/DC	Amorolfine 5% Medicated Nail Lacquer	POM
PL 13931/0081	UK/H/4509/001/DC	Amorolfine hydrochloride 5% w/v Medicated Nail Lacquer	POM
PL 13931/0083	UK/H/4508/001/DC	Amorolfine 5% w/v Medicated Nail Lacquer	POM
PL 13931/0073	UK/H/4506/001/DC	Amorolfine 5% w/v Medicated Nail Lacquer	P
PL 13931/0076	UK/H/4514/001/DC	Amorolfine 5% w/v Medicated Nail Lacquer	P
PL 13931/0078	UK/H/4513/001DC	Amorolfine 5% w/v Medicated Nail Lacquer	P
PL 13931/0079	UK/H/4515/001/DC	Tinecur 5% w/v Medicated Nail Lacquer	P
PL 13931/0080	UK/H/4516/001/DC	Amorstad 5% w/v Medicated Nail Lacquer	P
PL 13931/0082	UK/H/4512/001/DC	Amorolfine 5% w/v Medicated Nail Lacquer	P

These are prescription (POM) and pharmacy (P) only medicines; the legal status for each licence is listed in the table above.

Amorolfine 5% w/v Nail Lacquer contains the active ingredient, amorolfine hydrochloride, which belongs to the antifungals for topical use. Amorolfine 5% w/v Nail Lacquer is used to treat fungal infections of the nails.

No new or unexpected safety concerns arose from these applications and it was therefore judged that the benefits of using Amorolfine 5% w/v Nail Lacquer outweigh the risks; hence Marketing Authorisations have been granted.

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Module 1

Product Name	Amorolfine 5% w/v Medicated Nail Lacquer Amorolfine 5% w/v Medicated Nail Lacquer Amorolfine hydrochloride 5% w/v Medicated Nail Lacquer Amorolfine 5% w/v Medicated Nail Lacquer Amorolfine 5% w/v Medicated Nail Lacquer Amorolfine 5% w/v Medicated Nail Lacquer Amorolfine 5% w/v Medicated Nail Lacquer Amorolfine 5% w/v Medicated Nail Lacquer Tinecur 5% w/v Medicated Nail Lacquer Amorstad 5% w/v Medicated Nail Lacquer
Type of Application	Generic, Article 10.3
Active Substance	Amorolfine Hydrochloride
Form	Topical Solution
Strength	5% w/v
Marketing Authorisation Holder	Chanelle Medical Loughrea, County Galway Ireland
Reference Member State (RMS)	UK
Concerned Member State (CMS)	UK/H/4506/001/DC-Germany UK/H/4507/001/DC-Finland, Portugal and Sweden UK/H/4508/001/DC-Belgium, France, Hungary, Portugal and Spain UK/H/4509/001/DC-Portugal and Spain UK/H/4510/001/DC-Greece UK/H/4512/001/DC-France and Germany UK/H/4513/001/DC-France, Germany and Luxembourg UK/H/4514/001/DC-Germany UK/H/4515/001/DC-Germany UK/H/4516/001/DC-Germany and Slovakia
Procedure Number	UK/H/4506-4510 & 4512-4516/001/DC
End of Procedure	10 th June 2011

Module 2

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Amorolfine 5% w/v Nail Lacquer (PL 13931/0075,77,81,83) are as follows: Differences are highlighted in yellow.

Please note that the following SmPCs are subject to medical prescription (POM).

1 NAME OF THE MEDICINAL PRODUCT

For PL 13931/0075	Amorolfine 5% w/v Medicated Nail Lacquer
For PL 13931/0077	Amorstad 5% Medicated Nail Lacquer
For PL 13931/0081	Amorolfine hydrochloride 5% w/v Medicated Nail Lacquer
For PL 13931/0083	Amorolfine 5% w/v Medicated Nail Lacquer

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 55.74 mg amorolfine hydrochloride (equivalent to 50 mg amorolfine).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated Nail Lacquer.

Clear, colourless to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Onychomycoses caused by dermatophytes, yeasts and moulds without nail matrix involvement.

4.2 Posology and method of administration

Posology

The nail lacquer should be applied to the affected finger or toe nails once weekly. Twice weekly application may prove beneficial in some cases.

The patient should apply the nail lacquer as follows:

1. Before the first application of Amorolfine 5% w/v Nail Lacquer, it is essential that the affected areas of nail (particularly the nail surfaces) should be filed down as thoroughly as possible using the nail file supplied. The surface of the nail should then be cleansed and degreased using an alcohol cleaning pad. Before repeat application of Amorolfine 5% w/v Nail Lacquer the affected nails should be filed down again as required, following cleansing with a cleaning pad to remove any remaining lacquer.

Caution: Nail files used for affected nails must not be used for healthy nails.

2. With one of the reusable applicators supplied, apply the nail lacquer to the entire surface of the affected nails. Allow the nail lacquer to dry for 3-5 minutes. After use, clean the applicator with the same cleaning pad used before for nail cleaning. Keep the bottle tightly closed.

For each nail to be treated, dip the applicator into the nail lacquer without wiping off any of the lacquer on the bottle neck.

Caution: When working with organic solvents (thinners, white spirit, etc.) wear impermeable gloves in order to protect the Amorolfine 5% w/v Nail Lacquer on the nails.

Treatment should be continued without interruption until the nail is regenerated and the affected areas are finally cured. The required frequency and duration of treatment depends essentially on intensity and localisation of the infection. In general, it is six months (finger nails) and nine to twelve months (toe nails). A review of the treatment is recommended at intervals of approximately three months.

Co-existent tinea pedis should be treated with an appropriate antimycotic cream.

Elderly

There are no specific dosage recommendations for use in elderly patients.

Children

Amorolfine 5% w/v Nail Lacquer is not recommended for use in children due to a lack of data on safety or efficacy.

Method of Administration

Cutaneous use.

4.3 Contraindications

Amorolfine 5% w/v Nail Lacquer must not be reused by patients who have shown hypersensitivity to the treatment.

Hypersensitivity to the active substance amorolfine or to any of the excipients.

4.4 Special warnings and precautions for use

Avoid contact of the lacquer with eyes, ears and mucous membranes.

Patients with underlying conditions predisposing to fungal nail infections should discuss appropriate treatment with a doctor. Such conditions include peripheral circulatory disorders, diabetes mellitus, and immunosuppression.

Patients with nail dystrophy and destroyed nail plate should discuss appropriate treatment with a doctor.

Use of nail varnish or artificial nails should be avoided during treatment.

As no clinical data is available, amorolfine is not recommended in children.

4.5 Interaction with other medicinal products and other forms of interaction

There are no specific studies involving concomitant treatment with other topical medicines.

4.6 Fertility, pregnancy and lactation

Pregnancy

For Amorolfine 5% w/v Nail Lacquer no clinical data on exposed pregnancies are available. Reproductive toxicology studies showed no evidence of teratogenicity in laboratory animals, but embryotoxicity was observed at high oral doses of amorolfine. Considering the low systemic exposure of amorolfine at the proposed clinical use, adverse effects on the fetus are not expected, however, as a precautionary measure it is preferable to avoid the use of Amorolfine 5% w/v Nail Lacquer during pregnancy.

Breastfeeding

No effects on the suckling child are anticipated since the systemic exposure of the breast-feeding women to amorolfine is negligible. Amorolfine 5% w/v Nail Lacquer can be used during breast-feeding.

4.7 Effects on ability to drive and use machines

Amorolfine 5% w/v Nail Lacquer has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse drug reactions are rare. Nail disorders (e.g. nail discoloration, broken nails, brittle nails) may occur. These reactions can also be linked to the onychomycosis itself.

System Organ Class	Frequency	Adverse drug reaction
Skin and subcutaneous tissue disorders	Rare ($\geq 1/10,000$ to $< 1/1,000$)	Nail disorder, nail discoloration, onychoclasia

	Very rare (<1/10,000)	Skin burning sensation, contact dermatitis
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4.9 Overdose

Accidental oral ingestion

Amorolfine 5% w/v Nail Lacquer is for topical use. In the event of accidental oral ingestion, an appropriate method of gastric emptying may be used.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotheapeutic group: Antifungals for dermatological use, other antifungals for topical use

ATC code: D01AE16

Amorolfine 5% w/v Nail Lacquer is a topical antifungal which contains the active ingredient amorolfine.

Its fungistatic and fungicidal efficacy is based on an alteration of the fungal cell membrane targeted primarily on sterol biosynthesis. The ergosterol content is reduced and at the same time unusual sterically nonplanar sterols accumulate. Amorolfine is a broad spectrum antimycotic. It is highly active against the current or casual agents of onychomycoses:

The yeasts:

* *Candida albicans* and other species of *Candida*.

- The dermatophytes:

* *Trichophyton rubrum*, *Trichophyton interdigitale* and *Trichophyton mentagrophytes*, and other species of *Trichophyton*,

* *Epidermophyton floccosum*,

* *Microsporum*.

- The moulds:

* *Scopulariopsis*.

- The slightly sensitive moulds:

* *Aspergillus*, *Fusarium*, *Mucorales*

- The dematiacea (black fungus):

* *Hendersonula*, *Alternaria*, *Cladosporium*.

5.2 Pharmacokinetic properties

Amorolfine from nail lacquer penetrates into and diffuses through the nail plate and is thus able to eradicate poorly accessible fungi in the nail bed. Systemic absorption of the active ingredient is very low with this type of application.

Following prolonged use of Amorolfine 5% w/v Nail Lacquer, there is no indication of drug accumulation in the body.

5.3 Preclinical safety data

There are no findings of relevance to the prescriber other than those mentioned elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Eudragit RL 100 (Ammonio Methacrylate Copolymer Type A)

Triacetin

Butyl acetate

Ethyl acetate

Ethanol, anhydrous

6.2 Incompatibilities

Not applicable.

- 6.3 Shelf life**
2 years.
- 6.4 Special precautions for storage**
Stored below 30°C. Protect from heat. Keep bottle tightly closed and upright.
- 6.5 Nature and contents of container**
Amber glass (type I or type III) bottle with a HDPE cap, PTFE liner and tamper evident ring. Each pack may also contain cleansing swabs, spatulas and / or nail files, as required.
- For PL 13931/0075
Pack size(s):
1 bottle packed with or without cleansing swabs, spatulas and / or nail files.
- For PL 13931/0077
2.5 ml, 3 ml and 5 ml:
1 bottle packed with cleansing swabs, spatulas and nail files.
- Not all pack sizes may be marketed.
- For PL 13931/0081
Pack size(s):
5 ml:
1 bottle packed with nail files, re-usable applicators and cleansing swabs.
- Not all pack sizes may be marketed.
- For PL 13931/0083
Pack size(s):
2.5 ml, 3 ml and 5 ml:
1 bottle packed with cleansing swabs, spatulas and nail files.
- Not all pack sizes may be marketed.
- 6.6 Special precautions for disposal**
No special requirements.
- 7 MARKETING AUTHORISATION HOLDER**
Chanelle Medical,
Loughrea,
Co. Galway,
Ireland.
- 8 MARKETING AUTHORISATION NUMBER(S)**
PL 13931/0075
PL 13931/0077
PL 13931/0081
PL 13931/0083
- 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
20/07/2011
- 10 DATE OF REVISION OF THE TEXT**
20/07/2011

The UK Summary of Product Characteristics (SmPC) for Amorolfine 5% w/v Nail Lacquer (PL 13931/0073,76,78,79,80,82) are as follows: Differences are highlighted in yellow.

Please note that the following SmPCs are not subject to medical prescription (P) but available under the supervision of a pharmacist.

1 NAME OF THE MEDICINAL PRODUCT

For PL 13931/0073	Amorolfine 5% w/v Medicated Nail Lacquer
For PL 13931/0076	Amorolfine 5% w/v Medicated Nail Lacquer
For PL 13931/0078	Amorolfine 5% w/v Medicated Nail Lacquer
For PL 13931/0079	Tinecur 5% w/v Medicated Nail Lacquer
For PL 13931/0080	Amorstad 5% w/v Medicated Nail Lacquer
For PL 13931/0082	Amorolfine 5% w/v Medicated Nail Lacquer

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 55.74 mg amorolfine hydrochloride (equivalent to 50 mg amorolfine).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated Nail Lacquer.

Clear, colourless to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Onychomycoses caused by dermatophytes, yeasts and moulds without nail matrix involvement.

Treatment of mild cases of distal and lateral subungual onychomycoses caused by dermatophytes, yeasts and moulds limited up to 2 nails.

4.2 Posology and method of administration

Posology

Adults and Elderly

The nail lacquer should be applied to the affected finger or toe nails once weekly. Twice weekly application may prove beneficial in some cases.

The patient should apply the nail lacquer as follows:

1. Before the first application of Amorolfine 5% w/v Medicated Nail Lacquer, it is essential that the affected areas of nail (particularly the nail surfaces) should be filed down as thoroughly as possible using the nail file supplied. The surface of the nail should then be cleansed and degreased using an alcohol cleaning pad. Before repeat application of Amorolfine 5% w/v Medicated Nail Lacquer, the affected nails should be filed down again as required, following cleansing with a cleaning pad to remove any remaining lacquer.

Caution: Nail files used for affected nails must not be used for healthy nails.

2. With one of the reusable applicators supplied, apply the nail lacquer to the entire surface of the affected nails. Allow the nail lacquer to dry for 3-5 minutes. After use, clean the applicator with the same cleaning pad used before for nail cleaning. Keep the bottle tightly closed.

For each nail to be treated, dip the applicator into the nail lacquer without wiping off any of the lacquer on the bottle neck.

Caution: When working with organic solvents (thinners, white spirit, etc.) wear impermeable gloves in order to protect the Amorolfine 5% w/v Medicated Nail Lacquer on the nails.

Treatment should be continued without interruption until the nail is regenerated and the affected areas are finally cured. The required frequency and duration of treatment depends essentially on intensity and

localisation of the infection. In general, it is six months (finger nails) and nine to twelve months (toe nails). A review of the treatment is recommended at intervals of approximately three months.

Co-existent tinea pedis should be treated with an appropriate antimycotic cream.

Children

Amorolfine 5% w/v Medicated Nail Lacquer is not recommended for use in children due to a lack of data on safety or efficacy.

Method of Administration

Cutaneous use.

4.3 Contraindications

Amorolfine 5% w/v Medicated Nail Lacquer must not be reused by patients who have shown hypersensitivity to the treatment.

Hypersensitivity to the active substance amorolfine or to any of the excipients.

4.4 Special warnings and precautions for use

Avoid contact of the lacquer with eyes, ears and mucous membranes.

Patients with underlying conditions predisposing to fungal nail infections should be referred to a doctor. Such conditions include peripheral circulatory disorders, diabetes mellitus, and immunosuppression.

Patients with nail dystrophy and destroyed nail plate should be referred to their doctor.

Use of nail varnish or artificial nails should be avoided during treatment.

As no clinical data is available, amorolfine is not recommended in children.

4.5 Interaction with other medicinal products and other forms of interaction

There are no specific studies involving concomitant treatment with other topical medicines.

4.6 Fertility, pregnancy and lactation

Pregnancy

For Amorolfine 5% w/v Medicated Nail Lacquer no clinical data on exposed pregnancies are available. Reproductive toxicology studies showed no evidence of teratogenicity in laboratory animals, but embryotoxicity was observed at high oral doses of amorolfine. Considering the low systemic exposure of amorolfine at the proposed clinical use, adverse effects on the fetus are not expected, however, as a precautionary measure it is preferable to avoid the use of Amorolfine 5% w/v Medicated Nail Lacquer during pregnancy.

Breastfeeding

No effects on the suckling child are anticipated since the systemic exposure of the breast-feeding women to amorolfine is negligible. Amorolfine 5% w/v Medicated Nail Lacquer can be used during breast-feeding.

4.7 Effects on ability to drive and use machines

Amorolfine 5% w/v Medicated Nail Lacquer has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse drug reactions are rare. Nail disorders (e.g. nail discoloration, broken nails, brittle nails) may occur. These reactions can also be linked to the onychomycosis itself.

System Organ Class	Frequency	Adverse drug reaction
Skin and subcutaneous tissue disorders	Rare (≥1/10,000 to <1/1,000)	Nail disorder, nail discoloration, onychoclasia
	Very rare (<1/10,000)	Skin burning sensation, contact

		dermatitis
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4.9 Overdose

Accidental oral ingestion

Amorolfine 5% w/v Medicated Nail Lacquer is for topical use. In the event of accidental oral ingestion, an appropriate method of gastric emptying may be used.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungals for dermatological use, other antifungals
for topical use

ATC code: D01AE16

Amorolfine 5% w/v Medicated Nail Lacquer is a topical antifungal which contains the active ingredient amorolfine.

Its fungistatic and fungicidal efficacy is based on an alteration of the fungal cell membrane targeted primarily on sterol biosynthesis. The ergosterol content is reduced and at the same time unusual sterically nonplanar sterols accumulate. Amorolfine is a broad spectrum antimycotic. It is highly active against the current or casual agents of onychomycoses:

- The yeasts:

* *Candida albicans* and other species of *Candida*.

- The dermatophytes:

* *Trichophyton rubrum*, *Trichophyton interdigitale* and *Trichophyton mentagrophytes*, and other species of *Trichophyton*,

* *Epidermophyton floccosum*,

* *Microsporum*.

- The moulds:

* *Scopulariopsis*.

- The slightly sensitive moulds:

* *Aspergillus*, *Fusarium*, *Mucorales*

- The dematiacea (black fungus):

* *Hendersonula*, *Alternaria*, *Cladosporium*.

5.2 Pharmacokinetic properties

Amorolfine from nail lacquer penetrates into and diffuses through the nail plate and is thus able to eradicate poorly accessible fungi in the nail bed. Systemic absorption of the active ingredient is very low with this type of application.

Following prolonged use of Amorolfine 5% w/v Medicated Nail Lacquer, there is no indication of drug accumulation in the body.

5.3 Preclinical safety data

There are no findings of relevance to the prescriber other than those mentioned elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Eudragit RL 100 (Ammonio Methacrylate Copolymer Type A)

Triacetin

Butyl acetate

Ethyl acetate

Ethanol, anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 30°C. Protect from heat. Keep bottle tightly closed and upright.

6.5 Nature and contents of container

Amber glass (type I or type III) bottle with a HDPE cap, PTFE liner and tamper evident ring. Each pack may also contain cleansing swabs, spatulas and / or nail files, as required.

For PL 13931/0073

Pack size(s):

2.5 ml, 3 ml and 5 ml:

1 bottle packed with or without cleansing swabs, spatulas and / or nail files.

Not all pack sizes may be marketed.

For PL 13931/0076

Pack size(s):

3 ml and 5 ml:

1 bottle packed with cleansing swabs, spatulas and nail files.

Not all pack sizes may be marketed.

For PL 13931/0078

Pack size(s):

2.5 ml, 3 ml and 5 ml:

1 bottle packed with cleansing swabs, spatulas and nail files.

Not all pack sizes may be marketed.

For PL 13931/0079

Pack size(s):

2.5 ml, 3 ml and 5 ml:

1 bottle packed with or without cleansing swabs, spatulas and / or nail files. >

Not all pack sizes may be marketed.

PL 13931/0080

Pack size(s):

2.5 ml, 3 ml and 5 ml:

1 bottle packed with or without cleansing swabs, spatulas and / or nail files. >

Not all pack sizes may be marketed.

PL 13931/0082

Pack size(s):

2.5 ml, 3 ml and 5 ml:

1 bottle packed with cleansing swabs, spatulas and nail files.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Medical,
Loughrea,
Co. Galway,
Ireland.

- 8** **MARKETING AUTHORISATION NUMBER(S)**
PL 13931/0073
PL 13931/0076
PL 13931/0078
PL 13931/0079
PL 13931/0080
PL 13931/0082
- 9** **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
20/07/2011
- 10** **DATE OF REVISION OF THE TEXT**
20/07/2011

Module 3

Product Information Leaflet

PL 13931/0075

PACKAGE LEAFLET: INFORMATION FOR THE USER

Amorolfine 5% w/v Medicated Nail Lacquer Amorolfine

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use < Invented Name > 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.
- You must contact a doctor if your symptoms worsen or do not improve within 3 months.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:

1. What Amorolfine 5% w/v Medicated Nail Lacquer is and what it is used for
2. Before you use Amorolfine 5% w/v Medicated Nail Lacquer
3. How to use Amorolfine 5% w/v Medicated Nail Lacquer
4. Possible side effects
5. How to store Amorolfine 5% w/v Medicated Nail Lacquer
6. Further information

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

- Amorolfine 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 in Amorolfine 5% w/v Medicated Nail Lacquer is amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals.
- Amorolfine 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. Before you use Amorolfine 5% w/v Medicated Nail Lacquer

Do not use Amorolfine 5% w/v Medicated Nail Lacquer if you are:

- allergic (hypersensitive) to amorolfine or any of the other ingredients of Amorolfine 5% w/v Medicated Nail Lacquer (see section 6 for other ingredients).
- under the age of 18.

Take special care with Amorolfine 5% w/v Medicated Nail Lacquer:

- 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 Amorolfine 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.

Using other medicines

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 Amorolfine 5% w/v Medicated Nail Lacquer.

Pregnancy and breast-feeding

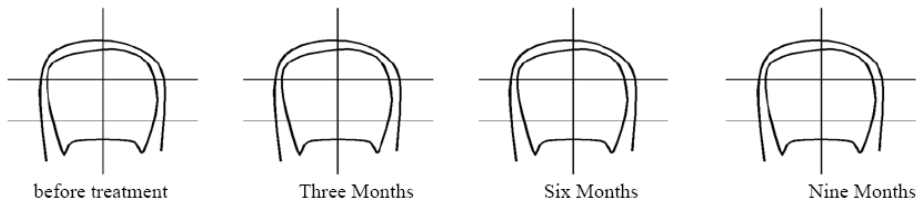
Tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding. Your doctor will then decide whether you should use Amorolfine 5% w/v Medicated Nail Lacquer. Ask your doctor or pharmacist for advice before taking any medicine.

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

Always use Amorolfine 5% w/v Medicated Nail Lacquer exactly as your doctor or pharmacist has told you. You should 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.
- 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.



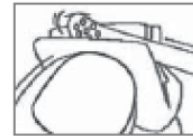
Step 3: Apply the lacquer

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 Amorolfine 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 Amorolfine 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 Amorolfine 5% w/v Medicated Nail Lacquer

Do not stop using Amorolfine 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, Amorolfine 5% w/v Medicated Nail Lacquer can cause side effects, although not everybody gets them.

Rare side effects (occurring in less than 1 in 1000 people)

Your nail may become discoloured or it may become loose or start to separate from the nail bed.

Very rare side effects (occurring in less than 1 in 10,000 people)

A burning sensation or allergic skin reaction (contact dermatitis) may occur in the area around the nail.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

- Keep out of the reach and sight of children.
- Do not use Amorolfine 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. Further information

What Amorolfine 5% w/v Medicated Nail Lacquer contains:

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

What Amorolfine 5% w/v Medicated Nail Lacquer looks like and contents of the pack

Amorolfine 5% w/v Medicated Nail Lacquer is a clear, colourless to pale yellow solution. It is available in

2.5 ml, 3 ml and 5 ml packs; 1 bottle packed with cleaning wipes, nail files and spatulas

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Chanelle Medical
Loughrea
Co. Galway
Ireland

This leaflet was last amended in: 04/2011

PL 13931/0082

Approved by: _____

PL 13931/0077

PACKAGE LEAFLET: INFORMATION FOR THE USER**Amorolfine 5% w/v Medicated Nail Lacquer
Amorolfine**

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others, it may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:

1. What Amorolfine 5% w/v Medicated Nail Lacquer is and what it is used for
2. Before you use Amorolfine 5% w/v Medicated Nail Lacquer
3. How to use Amorolfine 5% w/v Medicated Nail Lacquer
4. Possible side effects
5. How to store Amorolfine 5% w/v Medicated Nail Lacquer
6. Further information

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

- Amorolfine 5% w/v Medicated Nail Lacquer is used to treat fungal infections of the nails.
- Amorolfine 5% w/v Medicated Nail Lacquer contains the active ingredient amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals.
- It kills a wide variety of fungi that can cause nail infections.

2. Before you use Amorolfine 5% w/v Medicated Nail Lacquer

Do not use Amorolfine 5% w/v Medicated Nail Lacquer if you are:

- allergic (hypersensitive) to amorolfine or any of the other ingredients of Amorolfine 5% w/v Medicated Nail Lacquer (see section 6 for other ingredients).

Take special care with Amorolfine 5% w/v Medicated Nail Lacquer:

- 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 Amorolfine 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.

Using other medicines

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 Amorolfine 5% w/v Medicated Nail Lacquer.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding. Your doctor will then decide whether you should use Amorolfine 5% w/v Medicated Nail Lacquer.



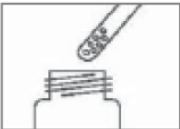


Ask your doctor or pharmacist for advice before taking any medicine.

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

Always use Amorolfine 5% w/v Medicated Nail Lacquer exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Amorolfine 5% w/v Medicated Nail Lacquer should be applied to the affected finger or toe nails once or twice a week exactly as directed by your doctor.

Instructions for use:

<p>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.</p>	
<p>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.</p>	
<p>Step 3: Take some lacquer from the bottle 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.</p>	
<p>Step 4: Apply the lacquer 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.</p>	
<p>Step 5: 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.</p>	

- 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 previously described.
- When dry, the nail lacquer is unaffected by soap and water, so you may 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 Amorolfine 5% w/v Medicated 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.

Your doctor will probably check how your treatment is progressing every 3 months or so.

If you accidentally swallow Amorolfine 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 Amorolfine 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 Amorolfine 5% w/v Medicated Nail Lacquer

Do not stop using Amorolfine 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, Amorolfine 5% w/v Medicated Nail Lacquer can cause side effects, although not everybody gets them.

Rare side effects (occurring in less than 1 in 1000 people)

Your nail may become discoloured or it may become loose or start to separate from the nail bed.

Very rare side effects (occurring in less than 1 in 10,000 people)

A burning sensation or allergic skin reaction (contact dermatitis) may occur in the area around the nail.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

- Keep out of the reach and sight of children.
- Do not use Amorolfine 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. Further information

What Amorolfine 5% w/v Medicated Nail Lacquer contains:

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

What Amorolfine 5% w/v Medicated Nail Lacquer looks like and contents of the pack

Amorolfine 5% w/v Medicated Nail Lacquer is a clear, colourless to pale yellow solution. It is available in

2.5ml, 3 ml and 5 ml packs; 1 bottle packed with cleansing swabs, spatulas and nail files.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Chanelle Medical, Loughrea, Co. Galway, Ireland

This leaflet was last approved in: 06/2011

PL 13931/0077

Approved by: _____

PL 13931/0081

PACKAGE LEAFLET: INFORMATION FOR THE USER**Amorolfine hydrochloride 5% w/v nail lacquer**

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others, it may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:

1. What Amorolfine hydrochloride 5% w/v is and what it is used for
2. Before you use Amorolfine hydrochloride 5% w/v
3. How to use Amorolfine hydrochloride 5% w/v
4. Possible side effects
5. How to store Amorolfine hydrochloride 5% w/v
6. Further information

1. What Amorolfine hydrochloride 5% w/v is and what it is used for

- Amorolfine hydrochloride 5% w/v is used to treat fungal infections of the nails.
- Amorolfine hydrochloride 5% w/v contains the active ingredient amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals.
- It kills a wide variety of fungi that can cause nail infections.

2. Before you use Amorolfine hydrochloride 5% w/v

Do not use Amorolfine hydrochloride 5% w/v if you are:

- allergic (hypersensitive) to amorolfine or any of the other ingredients of Amorolfine hydrochloride 5% w/v (see section 6 for other ingredients).

Take special care with Amorolfine hydrochloride 5% w/v:

- 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 Amorolfine hydrochloride 5% w/v 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.

Using other medicines

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 Amorolfine hydrochloride 5% w/v.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding. Your doctor will then decide whether you should use Amorolfine hydrochloride 5% w/v.



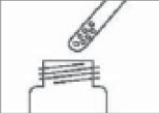


Ask your doctor or pharmacist for advice before taking any medicine.

3. How to use Amorolfine hydrochloride 5% w/v

Always use Amorolfine hydrochloride 5% w/v exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Amorolfine hydrochloride 5% w/v should be applied to the affected finger or toe nails once or twice a week exactly as directed by your doctor.

Instructions for use:

<p>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.</p>	
<p>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.</p>	
<p>Step 3: Take some lacquer from the bottle 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.</p>	
<p>Step 4: Apply the lacquer 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.</p>	
<p>Step 5: 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.</p>	

- 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 previously described.
- When dry, the nail lacquer is unaffected by soap and water, so you may 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 Amorolfine hydrochloride 5% w/v 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.

Your doctor will probably check how your treatment is progressing every 3 months or so.

If you accidentally swallow Amorolfine hydrochloride 5% w/v

If you, or anyone else, accidentally swallows the lacquer contact your doctor, pharmacist or nearest hospital straight away.

If you forget to use Amorolfine hydrochloride 5% w/v

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 Amorolfine hydrochloride 5% w/v

Do not stop using Amorolfine hydrochloride 5% w/v 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, Amorolfine hydrochloride 5% w/v can cause side effects, although not everybody gets them.

Rare side effects (occurring in less than 1 in 1000 people)

Your nail may become discoloured or it may become loose or start to separate from the nail bed.

Very rare side effects (occurring in less than 1 in 10,000 people)

A burning sensation or allergic skin reaction (contact dermatitis) may occur in the area around the nail.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Amorolfine hydrochloride 5% w/v

- Keep out of the reach and sight of children.
- Do not use Amorolfine hydrochloride 5% w/v 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. Further information

What Amorolfine hydrochloride 5% w/v contains:

Amorolfine hydrochloride 5% w/v contains 50 mg/ml of the active substance amorolfine (equivalent to 55.74 mg/ml amorolfine hydrochloride). The other ingredients are Eudragit RL 100 (ammonio methacrylate copolymer A), triacetin, butyl acetate, ethyl acetate and ethanol (anhydrous).

What Amorolfine hydrochloride 5% w/v looks like and contents of the pack

Amorolfine hydrochloride 5% w/v is a clear, colourless to pale yellow solution. It is available in a 5 ml pack; 1 bottle packed with or without cleansing swabs, spatulas and / or nail files.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is Chanelle Medical, Loughrea, Co. Galway, Ireland.
The manufacturer is Chanelle Medical, Loughrea, Co. Galway, Ireland.

This leaflet was last approved in: 06/2011

PL 13931/0083

**AMOROLFINE 5 % w/v
MEDICATED NAIL LACQUER
Amorolfine**

**PACKAGE LEAFLET: INFORMATION
FOR THE USER**

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others, it may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

IN THIS LEAFLET:

1. What Amorolfine 5% w/v Medicated Nail Lacquer is and what it is used for
2. Before you use Amorolfine 5% w/v Medicated Nail Lacquer
3. How to use Amorolfine 5% w/v Medicated Nail Lacquer
4. Possible side effects
5. How to store Amorolfine 5% w/v Medicated Nail Lacquer
6. Further information

1 WHAT AMOROLFINE 5% w/v MEDICATED NAIL LACQUER IS AND WHAT IT IS USED FOR

- Amorolfine 5% w/v Medicated Nail Lacquer is used to treat fungal infections of the nails
- Amorolfine 5% w/v Medicated Nail Lacquer contains the active ingredient amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals
- It kills a wide variety of fungi that can cause nail infections.

2 BEFORE YOU USE AMOROLFINE 5% w/v MEDICATED NAIL LACQUER

Do not use Amorolfine 5% w/v Medicated Nail Lacquer if you are:

- allergic (hypersensitive) to amorolfine or any of the other ingredients of Amorolfine 5% w/v Medicated Nail Lacquer (see section 6 for other ingredients).

Take special care with Amorolfine 5% w/v Medicated Nail Lacquer:

- 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 Amorolfine 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.

Using other medicines

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 Amorolfine 5% w/v Medicated Nail Lacquer.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding. Your doctor will then decide whether you should use Amorolfine 5% w/v Medicated Nail Lacquer. Ask your doctor or pharmacist for advice before taking any medicine.

3 HOW TO USE AMOROLFINE 5% w/v MEDICATED NAIL LACQUER

Always use Amorolfine 5% w/v Medicated Nail Lacquer exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Amorolfine 5% w/v Medicated Nail Lacquer should be applied to the affected finger or toe nails once or twice a week exactly 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 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: Take some lacquer from the bottle

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.



Step 4: Apply the lacquer

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 5: 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 previously described.
- When dry, the nail lacquer is unaffected by soap and water, so you may 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 Amorolfine 5% w/v Medicated 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.

Your doctor will probably check how your treatment is progressing every 3 months or so.

If you accidentally swallow Amorolfine 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 Amorolfine 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 Amorolfine 5% w/v Medicated Nail Lacquer

Do not stop using Amorolfine 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, Amorolfine 5% w/v Medicated Nail Lacquer can cause side effects, although not everybody gets them.

Rare side effects (occurring in less than 1 in 1000 people)

Your nail may become discoloured or it may become loose or start to separate from the nail bed.

Very rare side effects (occurring in less than 1 in 10,000 people)

A burning sensation or allergic skin reaction (contact dermatitis) may occur in the area around the nail.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 HOW TO STORE AMOROLFINE 5% w/v MEDICATED NAIL LACQUER

- Keep out of the reach and sight of children.
- Do not use Amorolfine 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 FURTHER INFORMATION**What Amorolfine 5% w/v Medicated Nail Lacquer contains:**

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

What Amorolfine 5% w/v Medicated Nail Lacquer looks like and contents of the pack

Amorolfine 5% w/v Medicated Nail Lacquer is a clear, colourless to pale yellow solution. It is available in 2.5 ml, 3 ml and 5 ml packs; 1 bottle packed with cleaning wipes, nail files and spatulas.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Chanelle Medical,
Loughrea,
Co. Galway,
Ireland.

This leaflet was last amended in: 06/2011

PL 13931/0083



19804-A

PL 13931/0073

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

**Amorolfine 5% w/v Medicated
Nail Lacquer**

Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to use Amorolfine 5% w/v carefully to get the best results from it.

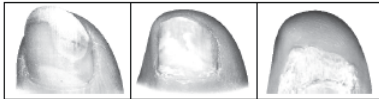
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve within 3 months.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:

1. What Amorolfine 5% w/v is and what it is used for
2. Before you use Amorolfine 5% w/v
3. How to use Amorolfine 5% w/v
4. Possible side effects
5. How to store Amorolfine 5% w/v
6. Further information

1. What Amorolfine 5% w/v is and what it is used for

- Amorolfine 5% w/v 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 in Amorolfine 5% w/v is amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals.
- Amorolfine 5% w/v 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. Before you use Amorolfine 5% w/v

Do not use Amorolfine 5% w/v if you are:

- allergic (hypersensitive) to amorolfine or any of the other ingredients of Amorolfine 5% w/v (see section 6 for other ingredients).
- under the age of 18.

Take special care with Amorolfine 5% w/v:

- 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 Amorolfine 5% w/v 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.

Using other medicines

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 Amorolfine 5% w/v.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding. Your doctor will then decide whether you should use Amorolfine 5% w/v. Ask your doctor or pharmacist for advice before taking any medicine.

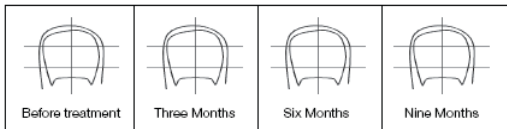
3. How to use Amorolfine 5% w/v

Always use Amorolfine 5% w/v exactly as your doctor or pharmacist has told you. You should 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.

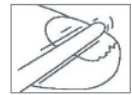


Instructions for use:

- 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.
- 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:

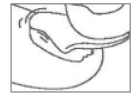
Step 1: File the Nail

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.

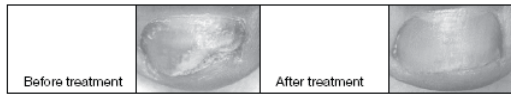


Step 4: Clean the applicator

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.



If you accidentally swallow Amorolfine 5% w/v

If you, or anyone else, accidentally swallows the lacquer contact your doctor, pharmacist or nearest hospital straight away.

If you forget to use Amorolfine 5% w/v

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 Amorolfine 5% w/v

Do not stop using Amorolfine 5% w/v 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, Amorolfine 5% w/v can cause side effects, although not everybody gets them.

Rare side effects (occurring in less than 1 in 1000 people)

Your nail may become discoloured or it may become loose or start to separate from the nail bed.

Very rare side effects (occurring in less than 1 in 10,000 people)

A burning sensation or allergic skin reaction (contact dermatitis) may occur in the area around the nail.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Amorolfine 5% w/v

- Keep out of the reach and sight of children.
- Do not use Amorolfine 5% w/v 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. Further information

What Amorolfine 5% w/v contains

Amorolfine 5% w/v nail lacquer contains 50 mg/ml of the active substance amorolfine (equivalent to 55.74 mg/ml amorolfine hydrochloride). The other ingredients are Eudragit RL 100 (ammonio methacrylate copolymer A), triacetin, butyl acetate, ethyl acetate and ethanol (anhydrous).

What Amorolfine 5% w/v looks like and contents of the pack

Amorolfine 5% w/v is a clear, colourless to pale yellow solution. It is available in 2.5ml, 3ml and 5ml packs; 1 bottle with or without cleansing swabs, spatulas and/or nail files. Not all pack sizes will be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is Chanelle Medical, Loughrea, Co Galway, Ireland. The manufacturer is Chanelle Medical, Loughrea, Co. Galway, Ireland.

This leaflet was approved in: 06/2011

PL 13931/0076

PACKAGE LEAFLET: INFORMATION FOR THE USER**Amorolfine 5% w/v Medicated Nail Lacquer
Amorolfine**

Read all of this leaflet carefully because it contains important information for you.

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

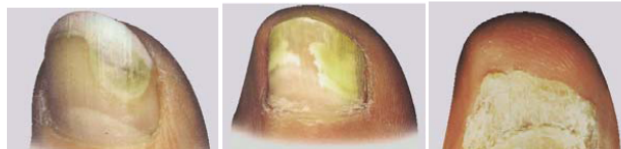
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve within 3 months.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:

1. What Amorolfine 5% w/v Medicated Nail Lacquer is and what it is used for
2. Before you use Amorolfine 5% w/v Medicated Nail Lacquer
3. How to use Amorolfine 5% w/v Medicated Nail Lacquer
4. Possible side effects
5. How to store Amorolfine 5% w/v Medicated Nail Lacquer
6. Further information

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

- Amorolfine 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 in Amorolfine 5% w/v Medicated Nail Lacquer is amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals.
- Amorolfine 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. Before you use Amorolfine 5% w/v Medicated Nail Lacquer****Do not use Amorolfine 5% w/v Medicated Nail Lacquer if you are:**

- allergic (hypersensitive) to amorolfine or any of the other ingredients of Amorolfine 5% w/v Medicated Nail Lacquer (see section 6 for other ingredients).
- under the age of 18.

Take special care with Amorolfine 5% w/v Medicated Nail Lacquer:

- 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 Amorolfine 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.

Using other medicines

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 Amorolfine 5% w/v Medicated Nail Lacquer.

Pregnancy and breast-feeding

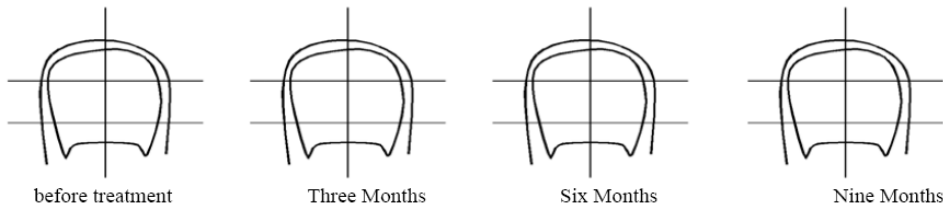
Tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding. Your doctor will then decide whether you should use Amorolfine 5% w/v Medicated Nail Lacquer. Ask your doctor or pharmacist for advice before taking any medicine.

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

Always use Amorolfine 5% w/v Medicated Nail Lacquer exactly as your doctor or pharmacist has told you. You should 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.
- 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.

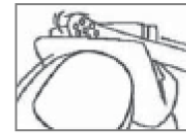


Step 3: Apply the lacquer

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 Amorolfine 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 Amorolfine 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 Amorolfine 5% w/v Medicated Nail Lacquer

Do not stop using Amorolfine 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, Amorolfine 5% w/v Medicated Nail Lacquer can cause side effects, although not everybody gets them.

Rare side effects (occurring in less than 1 in 1000 people)

Your nail may become discoloured or it may become loose or start to separate from the nail bed.

Very rare side effects (occurring in less than 1 in 10,000 people)

A burning sensation or allergic skin reaction (contact dermatitis) may occur in the area around the nail.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

- Keep out of the reach and sight of children.
- Do not use Amorolfine 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. Further information

What Amorolfine 5% w/v Medicated Nail Lacquer contains:

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

What Amorolfine 5% w/v Medicated Nail Lacquer looks like and contents of the pack

Amorolfine 5% w/v Medicated Nail Lacquer is a clear, colourless to pale yellow solution. It is available in

3 ml and 5 ml packs; 1 bottle packed with cleansing swabs, spatulas and nail files.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is Chanelle Medical, Loughrea, Co. Galway, Ireland
The manufacturer is Chanelle Medical, Loughrea, Co. Galway, Ireland

This leaflet was last approved in: 06/2011

PL 13931/0076

Approved by: _____

PACKAGE LEAFLET: INFORMATION FOR THE USER**Amorolfine 5% w/v Medicated Nail Lacquer
Amorolfine**

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Amorolfine 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.
- You must contact a doctor if your symptoms worsen or do not improve within 3 months.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:

1. What Amorolfine 5% w/v Medicated Nail Lacquer is and what it is used for
2. Before you use Amorolfine 5% w/v Medicated Nail Lacquer
3. How to use Amorolfine 5% w/v Medicated Nail Lacquer
4. Possible side effects
5. How to store Amorolfine 5% w/v Medicated Nail Lacquer
6. Further information

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

- Amorolfine 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 in Amorolfine 5% w/v Medicated Nail Lacquer is amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals.
- Amorolfine 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. Before you use Amorolfine 5% w/v Medicated Nail Lacquer**

Do not use Amorolfine 5% w/v Medicated Nail Lacquer if you are:

- allergic (hypersensitive) to amorolfine or any of the other ingredients of Amorolfine 5% w/v Medicated Nail Lacquer (see section 6 for other ingredients).
- under the age of 18.

Take special care with Amorolfine 5% w/v Medicated Nail Lacquer:

- 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 Amorolfine 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.

Using other medicines

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 Amorolfine 5% w/v Medicated Nail Lacquer.

Pregnancy and breast-feeding

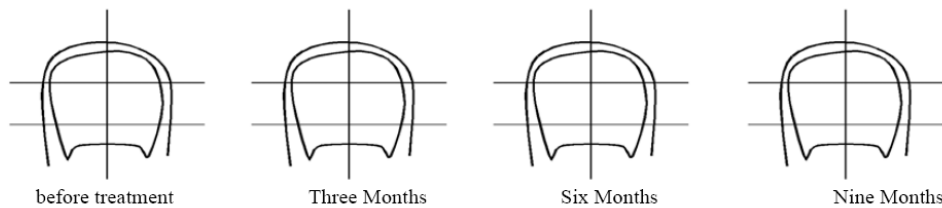
Tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding. Your doctor will then decide whether you should use Amorolfine 5% w/v Medicated Nail Lacquer. Ask your doctor or pharmacist for advice before taking any medicine.

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

Always use Amorolfine 5% w/v Medicated Nail Lacquer exactly as your doctor or pharmacist has told you. You should 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.
- 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 Amorolfine 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 Amorolfine 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 Amorolfine 5% w/v Medicated Nail Lacquer

Do not stop using Amorolfine 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, Amorolfine 5% w/v Medicated Nail Lacquer can cause side effects, although not everybody gets them.

Rare side effects (occurring in less than 1 in 1000 people)

Your nail may become discoloured or it may become loose or start to separate from the nail bed.

Very rare side effects (occurring in less than 1 in 10,000 people)

A burning sensation or allergic skin reaction (contact dermatitis) may occur in the area around the nail.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

- Keep out of the reach and sight of children.
- Do not use Amorolfine 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. Further information

What Amorolfine 5% w/v Medicated Nail Lacquer contains:

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

What Amorolfine 5% w/v Medicated Nail Lacquer looks like and contents of the pack

Amorolfine 5% w/v Medicated Nail Lacquer is a clear, colourless to pale yellow solution. It is available in

2.5 ml, 3 ml and 5 ml packs; 1 bottle packed with cleansing swabs, spatulas and nail files.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is Chanelle Medical, Loughrea, Co. Galway, Ireland
The manufacturer is Chanelle Medical, Loughrea, Co. Galway, Ireland.

This leaflet was last approved in: 06/2011

PL 13931/0078

Approved by: _____

PL 13931/0079

PACKAGE LEAFLET: INFORMATION FOR THE USER**Tinecur 5% w/v Medicated Nail Lacquer
Amorolfine**

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Tinecur 5% w/v 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.
- You must contact a doctor if your symptoms worsen or do not improve within 3 months.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:

1. What Tinecur 5% w/v is and what it is used for
2. Before you use Tinecur 5% w/v
3. How to use Tinecur 5% w/v
4. Possible side effects
5. How to store Tinecur 5% w/v
6. Further information

1. What Tinecur 5% w/v is and what it is used for

- Tinecur 5% w/v 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 in Tinecur 5% w/v is amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals.
- Tinecur 5% w/v 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. Before you use Tinecur 5% w/v****Do not use Tinecur 5% w/v if you are:**

- allergic (hypersensitive) to amorolfine or any of the other ingredients of Tinecur 5% w/v (see section 6 for other ingredients).
- under the age of 18.

Take special care with Tinecur 5% w/v:

- 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 Tinecur 5% w/v 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.

Using other medicines

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 Tinecur 5% w/v.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding. Your doctor will then decide whether you should use Tinecur 5% w/v.

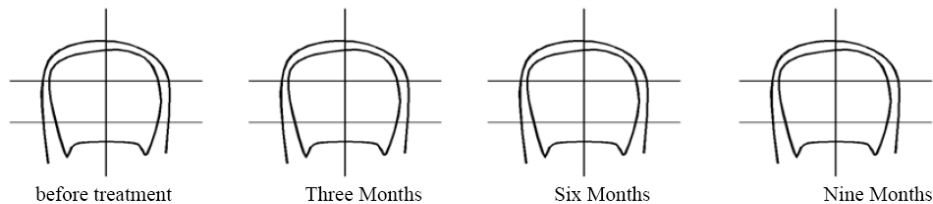
Ask your doctor or pharmacist for advice before taking any medicine.

3. How to use Tinecur 5% w/v

Always use Tinecur 5% w/v exactly as your doctor or pharmacist has told you. You should 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.
- 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 Tinecur 5% w/v

If you, or anyone else, accidentally swallows the lacquer contact your doctor, pharmacist or nearest hospital straight away.

If you forget to use Tinecur 5% w/v

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 Tinecur 5% w/v

Do not stop using Tinecur 5% w/v 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, Tinecur 5% w/v can cause side effects, although not everybody gets them.

Rare side effects (occurring in less than 1 in 1000 people)

Your nail may become discoloured or it may become loose or start to separate from the nail bed.

Very rare side effects (occurring in less than 1 in 10,000 people)

A burning sensation or allergic skin reaction (contact dermatitis) may occur in the area around the nail.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Tinecur 5% w/v

- Keep out of the reach and sight of children.
- Do not use Tinecur 5% w/v 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. Further information

What Tinecur 5% w/v contains:

Tinecur 5% w/v contains 50 mg/ml of the active substance amorolfine (equivalent to 55.74 mg/ml amorolfine hydrochloride). The other ingredients are Eudragit RL 100 (ammonio methacrylate copolymer A), triacetin, butyl acetate, ethyl acetate and ethanol (anhydrous).

What Tinecur 5% w/v looks like and contents of the pack

Tinecur 5% w/v is a clear, colourless to pale yellow solution. It is available in 2.5 ml, 3 ml and 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 Chanelle Medical, Loughrea, Co. Galway, Ireland.
The manufacturer is Chanelle Medical, Loughrea, Co. Galway, Ireland.

This leaflet was last approved in: 06/2011

Approved by: _____

PL 13931/0080

PACKAGE LEAFLET: INFORMATION FOR THE USER**Amorstad 5% w/v Medicated Nail Lacquer
Amorolfine**

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Amorstad 5% w/v 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.
- You must contact a doctor if your symptoms worsen or do not improve within 3 months.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:

1. What Amorstad 5% w/v is and what it is used for
2. Before you use Amorstad 5% w/v
3. How to use Amorstad 5% w/v
4. Possible side effects
5. How to store Amorstad 5% w/v
6. Further information

1. What Amorstad 5% w/v is and what it is used for

- Amorstad 5% w/v 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 in Amorstad 5% w/v is amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals.
- Amorstad 5% w/v 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. Before you use Amorstad 5% w/v****Do not use Amorstad 5% w/v if you are:**

- allergic (hypersensitive) to amorolfine or any of the other ingredients of Amorstad 5% w/v (see section 6 for other ingredients).
- under the age of 18.

Take special care with Amorstad 5% w/v:

- 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 Amorstad 5% w/v 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.

Using other medicines

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 Amorstad 5% w/v.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding. Your doctor will then decide whether you should use Amorstad 5% w/v.

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

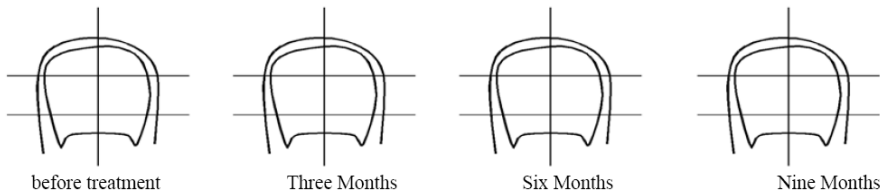
3. How to use Amorstad 5% w/v

Always use Amorstad 5% w/v exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and the Elderly

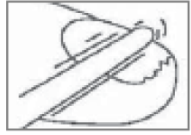

Before Commencing Treatment:

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.
- 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:

<p>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.</p>	
<p>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.</p>	

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 Amorstad 5% w/v

If you, or anyone else, accidentally swallows the lacquer contact your doctor, pharmacist or nearest hospital straight away.

If you forget to use Amorstad 5% w/v

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 Amorstad 5% w/v

Do not stop using Amorstad 5% w/v 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, Amorstad 5% w/v can cause side effects, although not everybody gets them.

Rare side effects (occurring in less than 1 in 1000 people)

Your nail may become discoloured or it may become loose or start to separate from the nail bed.

Very rare side effects (occurring in less than 1 in 10,000 people)

A burning sensation or allergic skin reaction (contact dermatitis) may occur in the area around the nail.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Amorstad 5% w/v

- Keep out of the reach and sight of children.
- Do not use Amorstad 5% w/v 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. Further information

What Amorstad 5% w/v contains:

Amorstad 5% w/v contains 50 mg/ml of the active substance amorolfine (equivalent to 55.74 mg /ml amorolfine hydrochloride). The other ingredients are Eudragit RL 100 (ammonio methacrylate copolymer A), triacetin, butyl acetate, ethyl acetate and ethanol (anhydrous).

What Amorstad 5% w/v looks like and contents of the pack

Amorstad 5% w/v is a clear, colourless to pale yellow solution. It is available in 2.5 ml, 3 ml and 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 Chanelle Medical, Loughrea, Co. Galway, Ireland.
The manufacturer is Chanelle Medical, Loughrea, Co. Galway, Ireland.

This leaflet was last approved in: 06/2011

Approved by: _____

PL 13931/0082

PACKAGE LEAFLET: INFORMATION FOR THE USER**Amorolfine 5% w/v Medicated Nail Lacquer
Amorolfine**

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use < Invented Name > 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.
- You must contact a doctor if your symptoms worsen or do not improve within 3 months.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:

1. What Amorolfine 5% w/v Medicated Nail Lacquer is and what it is used for
2. Before you use Amorolfine 5% w/v Medicated Nail Lacquer
3. How to use Amorolfine 5% w/v Medicated Nail Lacquer
4. Possible side effects
5. How to store Amorolfine 5% w/v Medicated Nail Lacquer
6. Further information

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

- Amorolfine 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 in Amorolfine 5% w/v Medicated Nail Lacquer is amorolfine (as the hydrochloride) which belongs to a group of medicines known as antifungals.
- Amorolfine 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. Before you use Amorolfine 5% w/v Medicated Nail Lacquer****Do not use Amorolfine 5% w/v Medicated Nail Lacquer if you are:**

- allergic (hypersensitive) to amorolfine or any of the other ingredients of Amorolfine 5% w/v Medicated Nail Lacquer (see section 6 for other ingredients).
- under the age of 18.

Take special care with Amorolfine 5% w/v Medicated Nail Lacquer:

- 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 Amorolfine 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.

Using other medicines

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 Amorolfine 5% w/v Medicated Nail Lacquer.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding. Your doctor will then decide whether you should use Amorolfine 5% w/v Medicated Nail Lacquer.

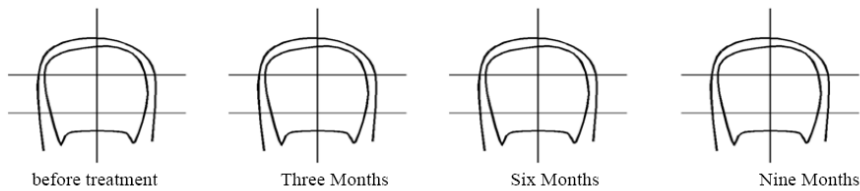
Ask your doctor or pharmacist for advice before taking any medicine.

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

Always use Amorolfine 5% w/v Medicated Nail Lacquer exactly as your doctor or pharmacist has told you. You should 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.
- 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 Amorolfine 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 Amorolfine 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 Amorolfine 5% w/v Medicated Nail Lacquer

Do not stop using Amorolfine 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, Amorolfine 5% w/v Medicated Nail Lacquer can cause side effects, although not everybody gets them.

Rare side effects (occurring in less than 1 in 1000 people)

Your nail may become discoloured or it may become loose or start to separate from the nail bed.

Very rare side effects (occurring in less than 1 in 10,000 people)

A burning sensation or allergic skin reaction (contact dermatitis) may occur in the area around the nail.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

- Keep out of the reach and sight of children.
- Do not use Amorolfine 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. Further information

What Amorolfine 5% w/v Medicated Nail Lacquer contains:

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

What Amorolfine 5% w/v Medicated Nail Lacquer looks like and contents of the pack

Amorolfine 5% w/v Medicated Nail Lacquer is a clear, colourless to pale yellow solution. It is available in

2.5 ml, 3 ml and 5 ml packs; 1 bottle packed with cleaning wipes, nail files and spatulas

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Chanelle Medical
Loughrea
Co. Galway
Ireland

This leaflet was last amended in: 04/2011

PL 13931/0082

Approved by: _____

Module 4 Labelling

PL 13931/0075

PARTICULARS TO APPEAR ON THE OUTER PACKAGING {CARTON}**1. Name of the medicinal product**

Amorolfine 5% w/v Medicated Nail Lacquer
Amorolfine

2. Statement of active substance(s)

Contains 50 mg/ml amorolfine (equivalent to 55.74 mg/ml amorolfine hydrochloride).

3. List of excipients

Excipients include Eudragit RL 100 (Ammonio Methacrylate Copolymer Type A), Triacetin, Butyl acetate, Ethyl acetate, Ethanol (anhydrous).

4. Pharmaceutical form and contents

Medicated Nail Lacquer

< 2.5 ml > < 3 ml > < 5 ml >
1 bottle packed with cleaning wipes, nail files and spatulas

5. Method and route of administration

For cutaneous use.
Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

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

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions

Store below 30°C.
Protect from heat.
Keep bottle tightly closed and upright.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

11. Name and address of the marketing authorisation holder

Chanelle Medical
Loughrea
Co. Galway
Ireland

12. Marketing authorisation number(s)

PL 13931/0075

13. Batch number

LOT

14. General classification for supply

P

15. Instructions on use

Use as directed by your doctor or pharmacist

16. Information in braille

Amorolfine 5% w/v Medicated Nail Lacquer

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING {LABEL}**1. Name of the medicinal product**

Amorolfine 5% w/v Medicated Nail Lacquer
Amorolfine

2. Statement of active substance(s)

5% amorolfine

3. List of excipients**4. Pharmaceutical form and contents**

Medicated Nail Lacquer

2.5 ml
3 ml
5 ml
7.5 ml
10 ml

5. Method and route of administration

For cutaneous use.
Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate****11. Name and address of the marketing authorisation holder.**

Chanelle Medical

Loughrea
Co. Galway
Ireland

12. Marketing authorisation number

PL 13931/0075

13. Batch number

LOT

14. General classification for supply

☐

15. Instructions on use

Use as directed by your doctor or pharmacist

16. Instructions in braille

Approved by: _____

PL 13931/0077

PARTICULARS TO APPEAR ON THE OUTER PACKAGING {CARTON}**1. Name of the medicinal product**

Amorolfine 5% w/v Medicated Nail Lacquer
Amorolfine

2. Statement of active substance(s)

Contains 50 mg/ml amorolfine (equivalent to 55.74 mg/ml amorolfine hydrochloride).

3. List of excipients

Excipients include Eudragit RL 100 (Ammonio Methacrylate Copolymer Type A), Triacetin, Butyl acetate, Ethyl acetate, Ethanol (anhydrous).

4. Pharmaceutical form and contents

Medicated Nail Lacquer

< 2.5 ml > < 3 ml > < 5 ml >

1 bottle packed with cleansing swabs, spatulas and nail files

5. Method and route(s) of administration

For cutaneous use.
Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

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

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions

Store below 30°C.
Protect from heat.
Keep bottle tightly closed and upright.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

11. Name and address of the marketing authorisation holder

Chanelle Medical
Loughrea
Co. Galway
Ireland

12. Marketing authorisation number(s)

PL 13931/0077

13. Batch number

Batch

14. General classification for supply

POM

15. Instructions on use

Use as directed by your doctor or pharmacist

16. Information in braille

Amorolfine 5% w/v Medicated Nail Lacquer

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING {LABEL}**1. Name of the medicinal product**

Amorolfine 5% w/v Medicated Nail Lacquer
Amorolfine

2. Statement of active substance(s)

5% amorolfine

3. List of excipients**4. Pharmaceutical form and contents**

2.5 ml
3 ml
5 ml
7.5 ml
10 ml

5. Method and route(s) of administration

For cutaneous use.
Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

UK only:

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate****11. Name and address of the marketing authorisation holder.**

Chanelle Medical
Loughrea

Co. Galway
Ireland

12. Marketing authorisation number

PL 13931/0077

13. Batch number

Batch

14. General classification for supply

POM

15. Instructions on use

Use as directed by your doctor or pharmacist

16. Instructions in braille

Approved by: _____

PL 13931/0081

PARTICULARS TO APPEAR ON THE OUTER PACKAGING {CARTON}**1. Name of the medicinal product**

Amorolfine hydrochloride 5% w/v nail lacquer

2. Statement of active substance(s)

Contains 50 mg/ml amorolfine (equivalent to 55.74 mg/ml amorolfine hydrochloride).

3. List of excipients

Excipients include Eudragit RL 100 (Ammonio Methacrylate Copolymer Type A), Triacetin, Butyl acetate, Ethyl acetate, Ethanol (anhydrous).

4. Pharmaceutical form and contents

Medicated Nail Lacquer.

5 ml

1 bottle < packed with nail files, re-usable applicators and cleansing swabs. >

5. Method and route(s) of administration

For cutaneous use.

Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary**This product is flammable!****Keep the solution away from fire and flames!**

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditionsStore below 30°C. Protect from heat.
Keep bottle tightly closed and upright.**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate****11. Name and address of the marketing authorisation holder**

MA Holder: Chanelle Medical, Loughrea, Co. Galway, Ireland.

Page 1 of 4

12. Marketing authorisation number(s)

MA No.: PL 13931/0081

13. Batch number

<Batch> <Lot> <BN> {number}

14. General classification for supply

POM

15. Instructions on use

Use only as directed by a physician.

16. Information in braille

Amorolfine hydrochloride 5% w/v

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING {LABEL}**1. Name of the medicinal product**

Amorolfine hydrochloride 5% w/v nail lacquer

2. Statement of active substance(s)

5% amorolfine.

3. List of excipients**4. Pharmaceutical form and contents**

Medicated Nail Lacquer.

5 ml

5. Method and route(s) of administrationFor cutaneous use.
Read the package leaflet before use.**6. Special warning that the medicinal product must be stored out of the reach and sight of children**

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate****11. Name and address of the marketing authorisation holder.**

MA Holder: Chanelle Medical, Loughrea, Co. Galway, Ireland.

12. Marketing authorisation number**13. Batch number**

<Batch> <Lot> <BN> {number}

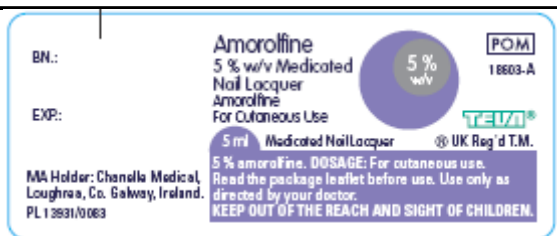
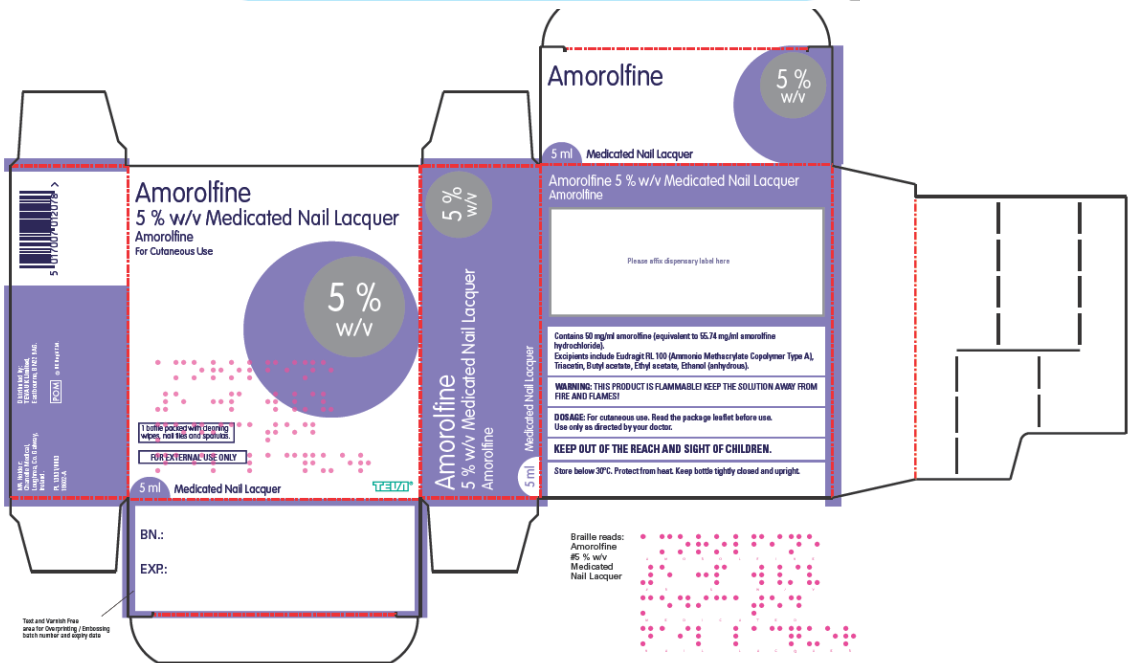
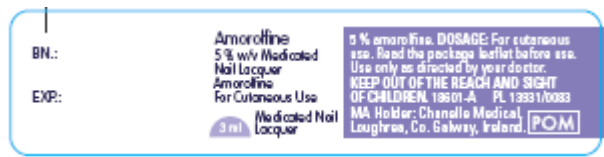
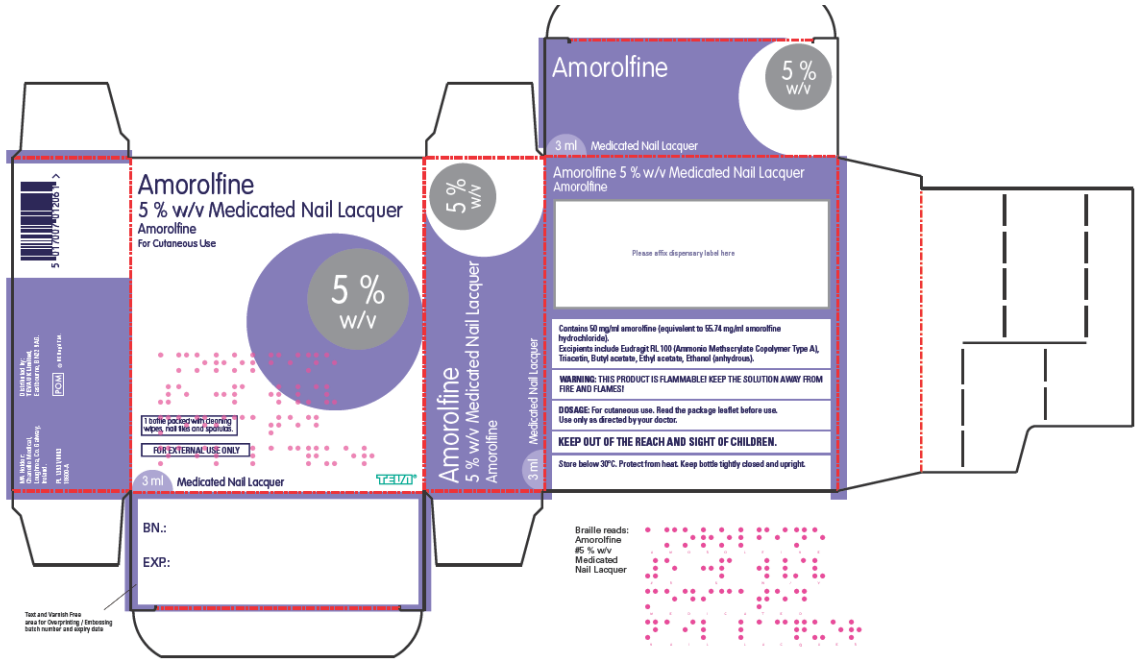
Page 3 of 4

14. General classification for supply

POM

15. Instructions on use**16. Instructions in braille**

PL 13931/0083



PL13931/0084

PARTICULARS TO APPEAR ON THE OUTER PACKAGING {CARTON}**1. Name of the medicinal product**

Amorolfine 5% w/v Medicated Nail Lacquer

2. Statement of active substance(s)

Contains 50 mg/ml amorolfine (equivalent to 55.74 mg/ml amorolfine hydrochloride).

3. List of excipients

Excipients include Eudragit RL 100 (Ammonio Methacrylate Copolymer Type A), Triacetin, Butyl acetate, Ethyl acetate, Ethanol (anhydrous).

4. Pharmaceutical form and contents

Medicated Nail Lacquer.

< 2.5 ml > < 3 ml > < 5 ml >

<1 bottle > < packed with nail files, re-usable applicators and cleansing swabs. >

< 7.5 ml > < 10 ml >

<2 bottles > < packed with nail files, re-usable applicators and cleansing swabs. >

5. Method and route(s) of administration

For cutaneous use.

Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary**This product is flammable!**
Keep the solution away from fire and flames!

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditionsStore below 30°C. Protect from heat.
Keep bottle tightly closed and upright.**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate****11. Name and address of the marketing authorisation holder**

Page 1 of 4

MA Holder: Chanelle Medical, Loughrea, Co. Galway, Ireland.

12. Marketing authorisation number(s)

MA No.: PL 13931/0084

13. Batch number

<Batch> <Lot> <BN> {number}

14. General classification for supply

POM

15. Instructions on use

Use only as directed by a physician.

16. Information in braille

Amorolfine 5% w/v Medicated Nail Lacquer

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING {LABEL}**1. Name of the medicinal product**

Amorolfine 5% w/v Medicated Nail Lacquer

2. Statement of active substance(s)

5% amorolfine.

3. List of excipients**4. Pharmaceutical form and contents**

Medicated Nail Lacquer.

2.5 ml

3 ml

5 ml

7.5 ml

10 ml

5. Method and route(s) of administration

For cutaneous use.

Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate****11. Name and address of the marketing authorisation holder.****MA Holder:** Chanelle Medical, Loughrea, Co. Galway, Ireland.**12. Marketing authorisation number**

Page 3 of 4

13. Batch number

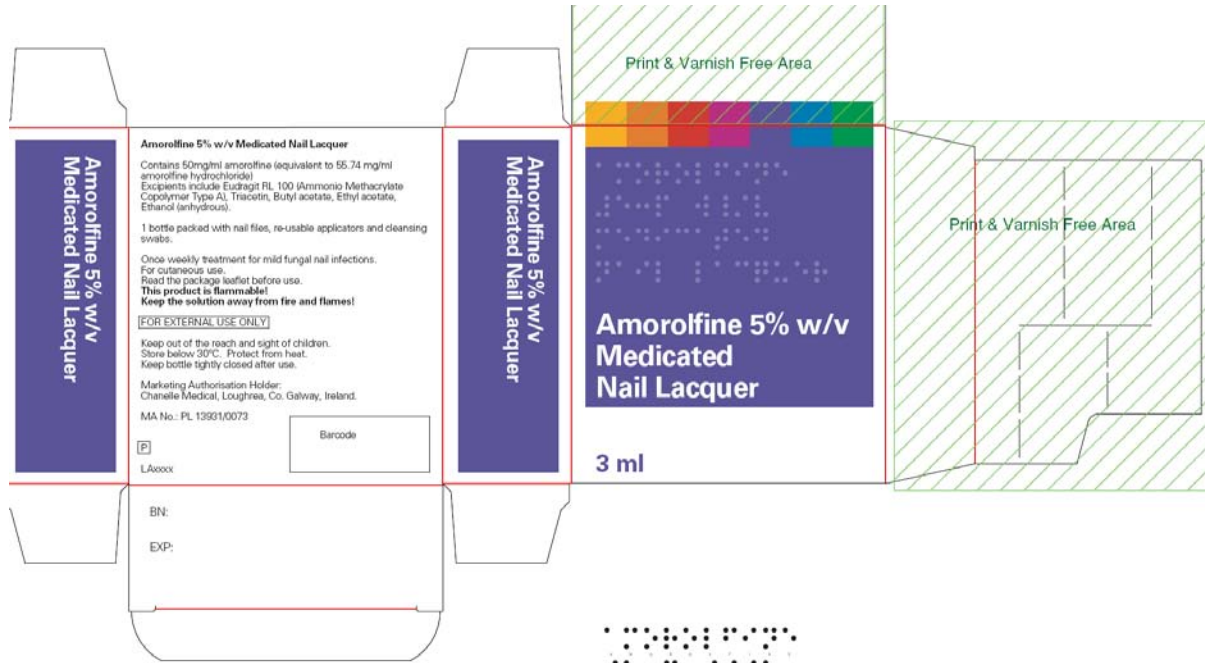
<Batch> <Lot> <BN> {number}

14. General classification for supply

POM

15. Instructions on use**16. Instructions in braille**

PL 13931/0073



3ml Label – 16 mm x 65 mm / Full Colour CMYK

PL 13931/0076**PARTICULARS TO APPEAR ON THE OUTER PACKAGING {CARTON}****1. Name of the medicinal product**

Amorolfine 5% w/v Medicated Nail Lacquer
Amorolfine

2. Statement of active substance(s)

Contains 50 mg/ml amorolfine (equivalent to 55.74 mg/ml amorolfine hydrochloride).

3. List of excipients

Excipients include Eudragit RL 100 (Ammonio Methacrylate Copolymer Type A), Triacetin, Butyl acetate, Ethyl acetate, Ethanol (anhydrous).

4. Pharmaceutical form and contents

Medicated Nail Lacquer

3 ml > < 5 ml >
1 bottle packed with cleansing swabs, spatulas and nail files

5. Method and route of administration

For cutaneous use.
Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

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

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions

Store below 30°C.
Protect from heat.
Keep bottle tightly closed and upright.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

11. Name and address of the marketing authorisation holder

Chanelle Medical
Loughrea
Co. Galway
Ireland

12. Marketing authorisation number(s)

PL 13931/0076

13. Batch number

Batch

14. General classification for supply

P

15. Instructions on use

Please read enclosed leaflet

16. Information in braille

Amorolfine 5% w/v Medicated Nail Lacquer

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING {LABEL}**1. Name of the medicinal product**

Amorolfine 5% w/v Medicated Nail Lacquer
Amorolfine

2. Statement of active substance(s)

5% amorolfine

3. List of excipients**4. Pharmaceutical form and contents**

Medicated Nail Lacquer

2.5 ml

3 ml

5 ml

7.5 ml

10 ml

5. Method and route of administration

For cutaneous use.
Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate****11. Name and address of the marketing authorisation holder.**

Chanelle Medical
Loughrea
Co. Galway
Ireland

12. Marketing authorisation number

PL 13931/0076

13. Batch number

Batch

14. General classification for supply

P

15. Instructions on use

Please read enclosed leaflet

16. Instructions in braille

PL 13931/0078**PARTICULARS TO APPEAR ON THE OUTER PACKAGING {CARTON}****1. Name of the medicinal product**

Amorolfine 5% w/v Medicated Nail Lacquer
Amorolfine

2. Statement of active substance(s)

Contains 50 mg/ml amorolfine (equivalent to 55.74 mg/ml amorolfine hydrochloride).

3. List of excipients

Excipients include Eudragit RL 100 (Ammonio Methacrylate Copolymer Type A), Triacetin, Butyl acetate, Ethyl acetate, Ethanol (anhydrous).

4. Pharmaceutical form and contents

Medicated Nail Lacquer

2.5 ml > < 3 ml > < 5 ml >

1 bottle packed with cleansing swabs, spatulas and nail files.

5. Method and route of administration

For cutaneous use.
Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

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

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions

Store below 30°C.
Protect from heat.
Keep bottle tightly closed and upright.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

11. Name and address of the marketing authorisation holder

Chanelle Medical
Loughrea
Co. Galway
Ireland

12. Marketing authorisation number(s)

PL 13931/0078

13. Batch number

Batch

14. General classification for supply

P

15. Instructions on use

Please read enclosed leaflet

16. Information in braille

Amorolfine 5% w/v/Medicated Nail Lacquer

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING {LABEL}**1. Name of the medicinal product**

Amorolfine 5% w/v/Medicated Nail Lacquer
Amorolfine

2. Statement of active substance(s)

5% amorolfine

3. List of excipients**4. Pharmaceutical form and contents**

Medicated Nail Lacquer

2.5 ml

3 ml

5 ml

7.5 ml

10 ml

5. Method and route of administration

For cutaneous use.
Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate****11. Name and address of the marketing authorisation holder.**

Chanelle Medical

Loughrea
Co. Galway
Ireland

12. Marketing authorisation number

PL 13931/0078

13. Batch number

Batch

14. General classification for supply

P

15. Instructions on use

Please see enclosed leaflet

16. Instructions in braille

PL 13931/0079

PARTICULARS TO APPEAR ON THE OUTER PACKAGING (CARTON)**1. Name of the medicinal product**

Tinecur 5% w/v Medicated Nail Lacquer
Amorolfine

2. Statement of active substance(s)

Contains 50 mg/ml amorolfine (equivalent to 55.74 mg/ml amorolfine hydrochloride).

3. List of excipients

Excipients include Eudragit RL 100 (Ammonio Methacrylate Copolymer Type A), Triacetin, Butyl acetate, Ethyl acetate, Ethanol (anhydrous).

4. Pharmaceutical form and contents

< 2,5 ml > < 3 ml > < 5 ml >
1 bottle < packed with nail files, re-usable applicators and cleansing swabs. >

5. Method and route of administration

For cutaneous use.
Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

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

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions

Store below 30°C. Protect from heat.
Keep bottle tightly closed and upright.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**11. Name and address of the marketing authorisation holder**

MA Holder: Chanelle Medical, Loughrea, Co. Galway, Ireland.

Page 1 of 4

12. Marketing authorisation number(s)

MA No: PL 13931/0079

13. Batch number

<Batch> <Lot> <BN> (number)

14. General classification for supply

P

15. Instructions on use

Once weekly treatment for mild fungal nail infections.

16. Information in braille

Tinecur 5% w/v

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING {LABEL}**1. Name of the medicinal product**

Tinecur 5% w/v Medicated Nail Lacquer

2. Statement of active substance(s)

5% amorolfine.

3. List of excipients**4. Pharmaceutical form and contents**

2.5 ml

3 ml

5 ml

5. Method and route of administration

For cutaneous use.

Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate****11. Name and address of the marketing authorisation holder.**

MA Holder: Chanelle Medical, Loughrea, Co. Galway, Ireland.

12. Marketing authorisation number**13. Batch number**

<Batch> <Lot> <BN> {number}

14. General classification for supply

P

15. Instructions on use

16. Instructions in braille

PL 13931/0080**PARTICULARS TO APPEAR ON THE OUTER PACKAGING {CARTON}****1. Name of the medicinal product**

Amorstad 5% w/v Medicated Nail Lacquer
Amorolfine

2. Statement of active substance(s)

Contains 50 mg/ml amorolfine (equivalent to 55.74 mg/ml amorolfine hydrochloride).

3. List of excipients

Excipients include Eudragit RL 100 (Ammonio Methacrylate Copolymer Type A), Triacetin, Butyl acetate, Ethyl acetate, Ethanol (anhydrous).

4. Pharmaceutical form and contents

< 2.5 ml > < 3 ml > < 5 ml >
1 bottle < packed with nail files, re-usable applicators and cleansing swabs. >

5. Method and route of administration

For cutaneous use.
Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

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

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions

Store below 30°C. Protect from heat.
Keep bottle tightly closed and upright.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**11. Name and address of the marketing authorisation holder**

MA Holder: Chanelle Medical, Loughrea, Co. Galway, Ireland.

12. Marketing authorisation number(s)

MA No: PL 13931/0080

13. Batch number

<Batch> <Lot> <BN> {number}

14. General classification for supply

P

15. Instructions on use

Once weekly treatment for mild fungal nail infections.

16. Information in braille

Amorstad 5% w/v

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING {LABEL}**1. Name of the medicinal product**

Amorstad 5% w/v Medicated Nail Lacquer

2. Statement of active substance(s)

5% amorolfine.

3. List of excipients**4. Pharmaceutical form and contents**

2.5 ml

3 ml

5 ml

5. Method and route of administration

For cutaneous use.

Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate****11. Name and address of the marketing authorisation holder.**

MA Holder: Chanelle Medical, Loughrea, Co. Galway, Ireland.

12. Marketing authorisation number**13. Batch number**

<Batch> <Lot> <BN> {number}

14. General classification for supply

P

15. Instructions on use

16. Instructions in braille

PL 13931/0082**PARTICULARS TO APPEAR ON THE OUTER PACKAGING {CARTON}****1. Name of the medicinal product**

Amorolfine 5% w/v Medicated Nail Lacquer
Amorolfine

2. Statement of active substance(s)

Contains 50 mg/ml amorolfine (equivalent to 55.74 mg/ml amorolfine hydrochloride).

3. List of excipients

Excipients include Eudragit RL 100 (Ammonio Methacrylate Copolymer Type A), Triacetin, Butyl acetate, Ethyl acetate, Ethanol (anhydrous).

4. Pharmaceutical form and contents

Medicated Nail Lacquer

< 2.5 ml > < 3 ml > < 5 ml >

1 bottle packed with cleaning wipes, nail files and spatulas

5. Method and route of administration

For cutaneous use.
Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

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

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions

Store below 30°C.
Protect from heat.
Keep bottle tightly closed and upright.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

11. Name and address of the marketing authorisation holder

Chanelle Medical
Loughrea
Co. Galway
Ireland

12. Marketing authorisation number(s)

PL 13931/0082

13. Batch number

LOT

14. General classification for supply

P

15. Instructions on use

Use as directed by your doctor or pharmacist

16. Information in braille

Amorolfine 5% w/v Medicated Nail Lacquer

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING {LABEL}**1. Name of the medicinal product**

Amorolfine 5% w/v Medicated Nail Lacquer
Amorolfine

2. Statement of active substance(s)

5% amorolfine

3. List of excipients**4. Pharmaceutical form and contents**

Medicated Nail Lacquer

2.5 ml
3 ml
5 ml
7.5 ml
10 ml

5. Method and route of administration

For cutaneous use.
Read the package leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

7. Other special warning(s), if necessary

FOR EXTERNAL USE ONLY

8. Expiry date

EXP:

9. Special storage conditions**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate****11. Name and address of the marketing authorisation holder.**

Chanelle Medical

Loughrea
Co. Galway
Ireland

12. Marketing authorisation number

PL13931/0082

13. Batch number

LOT

14. General classification for supply

P

15. Instructions on use

Use as directed by your doctor or pharmacist

16. Instructions in braille

Module 5

Scientific discussion during initial procedure

I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Chanelle Medical Marketing Authorisations (MAs) for the medical product Amorolfine 5% w/v Nail Lacquer, and associated trade names (PL 13931/0073, PL 13931//0075-83; UK/H/4506-4510 & 4512-4516) on 10th June 2011. These products are prescription and pharmacy only medicines; the legal status assigned to each licence is listed on page 2 of this report. The prescription-only medicines are indicated for onychomycoses caused by dermatophytes, yeasts and moulds without nail matrix involvement. The pharmacy-only medicines are indicated for both the former indication and the treatment of mild cases of distal and lateral subungual onychomycoses caused by dermatophytes, yeasts and moulds limited up to 2 nails.

These are abridged applications for Amorolfine 5% w/v Nail Lacquer, submitted under Article 10.3 of Directive 2001/83/EC, as amended, making reference to the licence for Loceryl Nail Lacquer 5% w/v; originally granted on 4th July 1991 to Roche Products Limited (PL 00031/0285). The reference licence has undergone a Change of Ownership (CoA) procedure and was authorised to the current MA Holder, Galderma UK Limited (PL 10590/0042) on 19th April 1999. The reference product has been authorised in the European Community for more than 10 years, so the period of data exclusivity has expired.

Amorolfine 5% w/v Nail Lacquer contains the active ingredient, amorolfine hydrochloride, belonging to the antifungals for topical use class of drugs (ATC code D01AE16). Amorolfine 5% w/v Nail Lacquer is a topical antifungal which contains the active ingredient amorolfine.

Its fungistatic and fungicidal efficacy is based on an alteration of the fungal cell membrane targeted primarily on sterol biosynthesis. The ergosterol content is reduced and at the same time unusual sterically nonplanar sterols accumulate. Amorolfine is a broad spectrum antimycotic. It is highly active against the current or casual agents of onychomycoses:

- yeasts
- dermatophytes
- moulds
- slightly sensitive moulds
- dematiacea (black fungus)

No new non-clinical or clinical efficacy studies were conducted for these applications, which is acceptable given that the application was for a generic version of product that has been licensed for over 10 years. A therapeutic equivalence study is not necessary to support these applications for an topical solution.

The RMS has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these product types at all sites responsible for the manufacture and assembly of these products. Evidence of compliance with GMP has been provided for the named manufacturing and assembly sites. For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For manufacturing sites outside the community, the RMS has accepted copies of current GMP certificates or satisfactory inspection summary reports, 'close-out letters' or 'exchange

of information' issued by the inspection services of the competent authorities (or those countries with which the EEA has a Mutual Recognition Agreement for their own territories) as certification that acceptable standards of GMP are in place at those non-Community sites.

The RMS considers that the pharmacovigilance system, as described by the MAH, fulfils the requirements and provides adequate evidence that the MAH has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country. The Marketing Authorisation Holder has provided adequate justification for not submitting a Risk Management Plan (RMP). As the application is for a generic version of an already authorised reference product, for which safety concerns requiring additional risk minimisation have not been identified, a risk minimisation system is not considered necessary. The reference product has been in use for many years and the safety profile of the active is well established.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environmental Risk Assessment (ERA). This was an application for a generic product and there is no reason to conclude that marketing of this product will change the overall use pattern of the existing market.

II. ABOUT THE PRODUCT

Name of the product in the Reference Member State	Amorolfine 5% w/v Medicated Nail Lacquer Amorolfine 5% w/v Medicated Nail Lacquer Amorolfine 5% w/v Medicated Nail Lacquer Amorolfine hydrochloride 5% w/v Nail Lacquer Amorolfine 5% w/v Medicated Nail Lacquer Amorolfine 5% w/v Medicated Nail Lacquer Amorolfine 5% w/v Medicated Nail Lacquer Amorolfine 5% w/v Medicated Nail Lacquer Tinecur 5% w/v Medicated Nail Lacquer Amorstad 5% w/v Medicated Nail Lacquer
Name(s) of the active substance(s) (INN)	Amorolfine hydrochloride
Pharmacotherapeutic classification (ATC code)	Other antifungals for topical use D01AE
Pharmaceutical form and strength(s)	Nail Lacquer, 5% w/v
Reference numbers for the Decentralised Procedure	UK/H/4506/001/DC-PL 13931/0073 UK/H/4507/001/DC-PL 13931/0077 UK/H/4508/001/DC-PL 13931/0083 UK/H/4509/001/DC-PL 13931/0081 UK/H/4510/001/DC-PL 13931/0075 UK/H/4512/001/DC-PL 13931/0082 UK/H/4513/001/DC-PL 13931/0078 UK/H/4514/001/DC-PL 13931/0076 UK/H/4515/001/DC-PL 13931/0079 UK/H/4516/001/DC-PL 13931/0080
Reference Member State	United Kingdom
Member States concerned	UK/H/4506/001/DC-Germany UK/H/4507/001/DC-Finland, Portugal and Sweden UK/H/4508/001/DC-Belgium, France, Hungary, Portugal and Spain UK/H/4509/001/DC-Portugal and Spain UK/H/4510/001/DC-Greece UK/H/4512/001/DC-France and Germany UK/H/4513/001/DC-France, Germany and Luxembourg UK/H/4514/001/DC-Germany UK/H/4515/001/DC-Germany UK/H/4516/001/DC-Germany and Slovakia
Marketing Authorisation Number(s)	PL 13931/0073 PL 13931/0077 PL 13931/0083 PL 13931/0081 PL 13931/0075 PL 13931/0082 PL 13931/0078 PL 13931/0076 PL 13931/0079 PL 13931/0080
Name and address of the authorisation holder	Chanelle Medical, Loughrea, County Galway, Ireland.

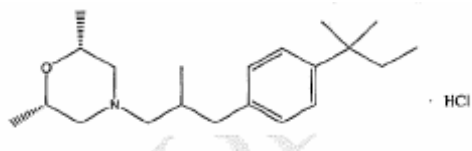
III SCIENTIFIC OVERVIEW AND DISCUSSION

III.1 QUALITY ASPECTS

DRUG SUBSTANCE

INN: Amorolfine hydrochloride
Chemical name: Cis-4-[4-(1,1-Dimethylpropyl)phenyl]-2-methylpropyl]-2,6-dimethylmorpholine hydrochloride

Structure:



Molecular formula: $C_{21}H_{35}NO.HCl$

Molecular weight: 353.98

General Properties

Description: White or almost-white crystals or crystalline powder
Solubility: Freely soluble in methanol and glacial acetic acid; soluble in ethanol, slightly soluble in acetonitrile, very slightly soluble in water

The active substance, amorolfine hydrochloride, is not the subject of a European Pharmacopoeia (Ph. Eur.) monograph.

Manufacture

Synthesis of the drug substance from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specifications are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Appropriate data have been supplied to characterise the active substance. All potential known impurities have been identified and characterised. Satisfactory certificates of analysis have been provided for all working standards. Batch analysis data are provided and comply with the proposed specification.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current guidelines concerning contact with foodstuffs.

Appropriate stability data have been generated to support a suitable re-test period when stored in the proposed packaging.

DRUG PRODUCT

Description and Composition

The product is presented as a clear, colourless to pale yellow solution. Each 1ml of solution contains 55.74 mg of the active substance amorolfine hydrochloride (equivalent to 50 mg amorolfine).

Other ingredients consist of pharmaceutical excipients, Eudragit RL 100 (Ammonio Methacrylate Copolymer Type A), triacetin, butyl acetate, ethyl acetate and anhydrous ethanol. Appropriate justifications for the inclusion of each excipient have been provided.

All excipients used comply with their respective European Pharmacopeial monograph with the exception of butyl acetate which is controlled to an in-house specification. Satisfactory Certificates of Analyses for each excipient has been provided. The applicant has provided a declaration confirming that there are no materials of human or animal origin contained in, or used in the manufacturing process for the proposed product. Furthermore, no genetically modified organisms are used in the manufacture of any of the excipients.

Pharmaceutical Development

The aim of the pharmaceutical development programme was to produce robust, reproducible product that could be considered generic medicinal product of Loceryl 5% w/v Medicated Nail Lacquer (Galderma UK Limited). Suitable pharmaceutical development data have been provided for these applications.

The physico-chemical properties of the drug product have been compared with the reference product. These data demonstrate that the proposed product can be considered a generic medicinal product of Loceryl 5% w/v Medicated Nail Lacquer (Galderma UK Limited).

Dissolution Profiles

Comparative dissolution data were provided for the test and reference products. The dissolution profiles were found to be similar.

Manufacture

A description and flow-chart of the manufacturing method has been provided.

In-process controls were considered appropriate considering the nature of the product and the method of manufacture. Process validation studies have been conducted and are accepted. Satisfactory analytical results from 4 commercial-scale batches were provided. All data were within specification.

Finished Product Specification

Finished product specifications are provided for both release and shelf-life, and are satisfactory; they provide an assurance of the quality and consistency of the finished product. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and adequately validated, as appropriate. Batch data are provided for 4 commercial-scale batches of the product, which demonstrate that the batches are compliant with the proposed release specifications. Certificates of Analysis have been provided for any reference standards used.

Container Closure System

The finished product is licensed for marketing in an amber glass (Type I or Type III) bottle with a high density polyethylene (HDPE) cap, polytetrafluoroethylene (PTFE) liner and tamper evident ring, which are placed with the Patient Information Leaflet (PIL) into cardboard outer cartons. Each pack may also contain cleansing swabs, spatulas and/or nail files, as required. The product is packaged in carton pack sizes of 2.5 mL, 3 mL, 5 mL, 7.5 mL (5 mL + 2.5 mL) and 10 mL (2 x 5 mL). The Marketing Authorisation Holder has stated that not all pack sizes may be marketed.

Specifications and Certificates of Analysis for all packaging components used have been provided. The glass bottles comply with Ph Eur requirements as well as the EU Directive 2002/72/EC.

Stability

Finished product stability studies have been conducted in accordance with current guidelines and results were within the proposed specification limits. Based on the results, a shelf-life of 2 years has been set which is satisfactory. Storage instructions are 'Store below 30°C', 'Protect from heat', and 'Keep bottle tightly closed and upright'.

Bioequivalence Study

A bioequivalence or therapeutic equivalence study has been waived on the basis that the proposed product is a solution for topical use and the active is not systemically absorbed. Comparative *in vitro* dissolution and other physico-chemical parameters have been presented and are essentially similar to the reference product Loceryl 5%w/v Nail Lacquer (Galderma UK Limited).

Quality Overall Summary

A satisfactory quality overview is provided and has been prepared by an appropriately qualified expert. The *curriculum vitae* of the expert has been provided.

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL), Labels

The SmPC, PIL and labelling are pharmaceutically acceptable. Colour mock-ups of the labelling and PIL have been provided. The labelling is satisfactory and fulfils the statutory requirements for Braille.

The applicant has submitted results of PIL user testing. The results indicate that the PIL is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

MAA Form

The MAA form is pharmaceutically satisfactory.

Conclusion

The test product is pharmaceutically equivalent to the reference product, which has been licensed in the UK for over 10 years. Given the route of administration and pharmaceutical form, it is not necessary to perform a therapeutic equivalence study.

There are no objections to the approval of Amorolfine 5% w/v Nail Lacquer from a pharmaceutical point of view.

III.2 NON-CLINICAL ASPECTS

The pharmacodynamic, pharmacokinetic and toxicological properties of amorolfine hydrochloride are well-known. Therefore, no further studies are required and the applicant has provided none.

The non-clinical overview was written by a suitably qualified person and is satisfactory. The *curriculum vitae* of the expert has been provided.

The SmPC is satisfactory from a pre-clinical viewpoint and is consistent with that for the reference product.

There are no objections to approval of Amorolfine 5%w/v Nail Lacquer from a non-clinical point of view.

III.3 CLINICAL ASPECTS

Pharmacokinetics

No new data have been submitted and none are required for applications of this type.

Amorolfine 5% w/v Nail Lacquer is a generic version Loceryl 5% w/v Nail Lacquer. The use of the reference products is well-established in the UK. Both the reference product and the test product contain the same quantitative and qualitative composition of the active ingredient, amorolfine hydrochloride.

According to CPMP guidelines, the applicant is not required to submit a bioequivalence study if the product is to be administered as a topical solution containing the same active substance, in the same concentration as the currently authorised product according to the Note for Guidance on the Investigation of Bioavailability and Bioequivalence (CPMP/EWP/QWP/1401/98) and applicant has submitted none which is satisfactory.

Pharmacodynamics

No new data have been submitted and none are required for applications of this type.

Clinical efficacy

No new data have been submitted and none are required for applications of this type.

Clinical safety

No new safety data have been submitted or required for these generic applications. As amorolfine hydrochloride is a well-known product with an acceptable adverse event profile, this is satisfactory.

Expert Report

A satisfactory clinical overview is provided, and has been prepared by an appropriately qualified physician. The *curriculum vitae* of the expert has been provided.

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL), Labels

The SmPC and PIL are medically acceptable, and consistent with those for the reference product. The labelling is medically acceptable and in-line with current requirements.

MAA form

The MAA form is medically satisfactory.

Conclusion

There are no objections to approval of Amorolfine 5% w/v Nail Lacquer, and associated brand-name versions, are generic versions of the reference product Loceryl 5% w/v Nail Lacquer from a clinical point of view.

IV OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT QUALITY

The important quality characteristics of Amorolfine 5% w/v Nail Lacquer are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL

No new non-clinical data were submitted and none are required for applications of this type.

EFFICACY

The applicant's product Amorolfine 5% w/v Nail Lacquer have been demonstrated to be a generic version of the reference product Loceryl Nail Lacquer 5% w/v (Galderma UK Limited).

No new or unexpected safety concerns arise from these applications.

PRODUCT LITERATURE

The SmPCs and PILs are acceptable, and consistent with those for the reference product. The labelling is acceptable and in-line with current requirements.

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

BENEFIT/RISK ASSESSMENT

The quality of the product is acceptable, and no new preclinical or clinical safety concerns have been identified. The qualitative and quantitative assessment supports the claim that the applicant's product Amorolfine 5% w/v Nail Lacquer and the reference product Loceryl Nail Lacquer 5% w/v (Galderma UK Limited), are interchangeable. Extensive clinical experience with amorolfine hydrochloride is considered to have demonstrated the therapeutic value of the active substance. The benefit/risk is, therefore, considered to be positive.

Module 6

STEPS TAKEN AFTER INITIAL PROCEDURE - SUMMARY

Date submitted	Application type	Scope	Outcome