Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Loceryl 5% w/v Medicated Nail Lacquer

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Loceryl nail lacquer contains 5% w/v amorolfine in the form of amorolfine hydrochloride.

Excipient with known effect:
One gram of nail lacquer contains 0.552 g alcohol (ethanol) which is equivalent to 55.2 % w/w.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated Nail Lacquer.

A clear colourless to almost colourless liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Onychomycoses caused by dermatophytes, yeasts and moulds.

4.2 Posology and method of administration

The nail lacquer should be applied to the affected finger or toe nails once weekly.

The patient should apply the nail lacquer as follows:

1.Before the first application of Loceryl, 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 a cleaning pad (as supplied). Before repeat application of Loceryl, 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 and allow it to dry. 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.

The required 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).

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

Paediatric Population
There are no specific dosage recommendations for children owing to the lack of clinical experience available to date.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

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

Caution: Loceryl nail lacquer should not be applied to the nail bed as it may cause localised effects such as contact dermatitis.

Owing to the lack of clinical experience available to date, children should not be treated with amorolfine 5% nail lacquer.
During the application of amorolfine no cosmetic nail lacquer or artificial nails shall be used.
When organic solvents are used impermeable gloves shall be used otherwise amorolfine nail lacquer will be removed.

A systemic or local allergic reaction could possibly occur after use of this product. If this happens, the product should be stopped immediately and medical advice should be sought.
Remove the product carefully by using a nail remover solution.
The product should not be reapplied.
This medicinal product contains 0.552 g alcohol (ethanol) per 1 g, which is equivalent to 55.2 % w/w. It may cause a burning sensation on damaged skin. Ethanol is a flammable substance and should not be used near an open flame, a lighted cigarette or some devices (e.g. hair dryers).

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

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

4.6 Fertility, pregnancy and lactation

Experience with amorolfine use during pregnancy and/or lactation is limited. Only a few cases of exposure to topical amorolfine use in pregnant women have been reported in the post-authorisation setting, therefore the potential risk is unknown. Studies in animals have shown reproductive toxicity at high oral doses; it is unknown whether amorolfine is excreted in human milk. Amorolfine should not be used during pregnancy and/or lactation unless clearly necessary.

4.7 Effects on ability to drive and use machines

Loceryl 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
Immune system disorders	Unknown frequency*	Hypersensitivity (systemic allergic reaction)*
Skin and subcutaneous tissue disorders	Rare (≥ 1/10000, < 1/1000)	Nail disorder, nail discoloration, onychoclasis (broken nails), onychorrhexis (brittle nails)
	Very rare (< 1/10000)	Skin burning sensation
	Unknown frequency*	Erythema*, pruritus*, contact dermatitis*, urticaria, blister*

* post marketing experience

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie.

4.9 Overdose

No systemic signs of overdose are expected following topical application of amorolfine 5% nail lacquer.
In case of accidental oral ingestion, appropriate symptomatic measures should be taken if needed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Other antifungals for topical use ATC code: D01AE16
Loceryl is a topical antimycotic. Amorolfine belongs to a new chemical class, and its fungicidal action 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 (MIC < 2mcg/ml) *in vitro* against
yeasts: Candida, Cryptococcus, Malassezia
dermatophytes: Trichophyton, Microsporum, Epidermophyton
moulds: Hendersonula, Alternaria, Scopulariopsis
dematiacea: Cladosporium, Fonsecaea, Wangiella
dimorphic fungi: Coccidioides, Histoplasma, Sporothrix

With the exception of *Actinomyces*, bacteria are not sensitive to amorolfine. *Propionibacterium acnes* is only slightly sensitive.

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 Loceryl Nail Lacquer, there is no indication of drug accumulation in the body.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ammonio methacrylate copolymer A
Triacetin
Butyl acetate
Ethyl acetate
Ethanol Anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C.
Protect from heat.
Keep bottle tightly closed after use.

6.5 Nature and contents of container

Amber glass type I bottle with screw thread and plastic screw closure.
Or

Amber glass type III bottle with screw thread and plastic screw closure with integrated applicator.

Pack sizes: 2.5ml (1 x 2.5ml)
5.0ml (1 x 5.0 ml)
7.5 ml (1 x 2.5ml & 1 x 5.0 ml)
10.0 ml (2 x 5.0ml)

All packs contain cleansing swabs and nail files.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Galderma International
La Défense 4 Tour Europlaza
20 Avenue André Prothin
Paris La Défense Cedex
92927
France

8 MARKETING AUTHORISATION NUMBER

PA22743/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th March 1993
Date of last renewal: 25th March 2008

10 DATE OF REVISION OF THE TEXT

May 2023