Summary of Product Characteristics

1. Name of the medicinal product

Loceryl®

2. Qualitative and quantitative composition

Amorolfine (as hydrochloride) 5% w/v.

This medicine contains 552 mg of alcohol (ethanol) per 1 g, which is equivalent to 55.2 % w/w.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Lacquer

4. Clinical particulars

4.1 Therapeutic indications

Topical treatment of onycomycosis caused by dermatophytes, yeast and moulds.

4.2 Posology and method of administration

Loceryl should be applied to the affected nails once or twice a week.

To apply the lacquer, the following recommendations should be carefully complied with:

a) Before the first application of Loceryl, the nails should be thoroughly cleaned. Using a nail file, the affected areas of the nail (particularly the surface), are filed down as much as possible.
Care must be taken not to file the periungual skin.

b) The surface of the nail should then be cleansed and degreased using a cleansing pad provided, and all remaining lacquer removed.

c) The lacquer is applied over the entire surface of the affected nail with the reusable applicator and the applicator cleaned before treating another nail to avoid contaminating the lacquer. The applicator must not be wiped off on the edge of the bottle.

d) The applicator is cleaned with one of the pads provided. The bottle must be kept tightly closed.

The same process is repeated for each affected nail.

Treatment should be continued without interruption until the nail is regenerated and the affected area is cured clinically and free of any fungus.

The required duration of treatment depends essentially on intensity and localization of the infection and the growth rate of the nails. In general, it is six months for finger nails and nine to twelve months for toenails.

Special instructions:

- The same nail files must not be used for healthy nails.
- Before each new application, the affected nail is filed if necessary, and always cleaned with the cleansing pads to eliminate any remaining lacquer.
- When working with organic solvents (thinners, white spirit, etc.), waterproof gloves must be worn to protect the layer of Loceryl on the nails.

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

Amorolfine 5% Nail Lacquer should not be applied on the skin around the nail. Avoid contact of the lacquer with eyes, ears and mucous membranes.

Owing to the lack of clinical experience available to date, children (under 18 years) should not be treated with amorolfine 5% nail lacquer.

During the application of amorolfine no artificial nails shall be used.

After applying amorolfine 5% nail lacquer, an interval of at least 10 min should be respected before application of any cosmetic nail lacquer.

Before repeat application of amorolfine 5% nail lacquer, the cosmetic nail lacquer should be removed carefully.

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 varnish remover solution.

The product should not be reapplied.

This medicine contains 552 mg 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 lit cigarette

or some devices (e.g. hair dryers).

Do not light a cigarette or expose to fire until the medicine has dried completely.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Use of 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 effects 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.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

https://sideeffects.health.gov.il/

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

5.3 Preclinical safety data

None stated.

6. Pharmaceutical particulars

6.1 List of excipients

Ethanol anhydrous; Ethyl acetate; Ammonio methacrylate copolymer, type A; Butyl acetate; Glycerol triacetate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C. Protect from heat. Keep bottle tightly closed after use. After first opening, the lacquer should be used within 6 months.

6.5 Nature and contents of container

Glass bottle: 2.5 ml with accessories (nail files, cleansing pads, applicators).

Glass bottle: 5 ml with accessories (nail files, cleansing pads, applicators).

Glass bottle: 2.5 ml with applicator cap, with accessories (nail files, cleansing pads).

Glass bottle: 5 ml with applicator cap, with accessories (nail files, cleansing pads).

Not all packs may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Manufacturer:

Laboratoires Galderma, Z.I. Montdesir 74 540 Alby Sur-Cheran, France.

8. Registration holder:

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Registration number: 133-12-30949-00

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