Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Curanail 5% w/v medicated nail lacquer

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Curanail nail lacquer contains 5% w/v (50 mg/ml) amorolfine in the form of amorolfine hydrochloride.
This medicine contains 0.552 g 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

Medicated nail lacquer.
A clear colourless to almost colourless liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology
Apply CURANAIL to the affected nails once a week.

Method of administration
To apply the nail lacquer, comply carefully with the following recommendations:
A. Before the first application of CURANAIL, clean the nails thoroughly. Remove any former varnish layers with a nail varnish remover; then using a nail file, file the surface of the nail (particularly the affected nail surface) as thoroughly as possible. Be careful not to file the periungual skin.
B. The surface of the nail should be cleansed and degreased using one of the cleaning swabs (supplied).
C. Apply the nail lacquer to the whole surface of the nail with one of the reusable applicators supplied. Between each nail application, clean the applicator with the cleaning swab supplied, thus avoiding any contamination of the nail lacquer. Do not wipe the applicator off on the edge of the bottle.
D. The applicator must be carefully cleaned with one of the swabs supplied after each application before treating another nail so as to avoid contamination of the lacquer.
E. If some nail lacquer has been put on the exterior of the stopper, please make sure to clean it with one of the cleaning swab supplied to avoid any contact with the skin.
F. Keep the bottle tightly closed.
Repeat the same process for each affected nail.
After each application of CURANAIL, it is important to wash your hands. However, when applying on fingernails, wait till it is completely dry before doing so.
Treatment should be continued without interruption until the nail is regenerated and the affected areas are finally cured.
In general, the duration of treatment is 6 months for fingernails and 9 months for toenails (it depends essentially on the intensity, localisation, growth rate of the nail, and extent of the infection).
After a 3-month use without improvement, a doctor should be consulted.

Special instructions:

- Do not reuse the nail files for healthy nails.

- Before each new application, remove any remaining lacquer, file the affected nails if required, and then always clean them with one of the cleansing swabs.

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

Special warnings:
CURANAIL should not be applied on the skin around the nail.
Avoid all contact of CURANAIL with eyes, ears or mucous membranes. Owing to the lack of clinical experience , children should not be treated with Curanail.
Patient care should be determined by a physician in patients suffering from peripheral vascular diseases, diabetes, immune system disorders, as well as in patients with nail dystrophy or seriously damaged nails (over two thirds of the nail plate is affected). In these cases, a systemic therapy should be envisaged.
Patients with a history of injury, skin conditions such as psoriasis or any other chronic skin condition, oedema, breathing disorders (Yellow nail syndrome), painful, distorted/deformed nails or any other symptoms should seek medical advice prior to commencing treatment.
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 medicine contains ethanol, it may cause a burning sensation on damaged skin.
This medicine contains ethanol, which is a flammable substance and should not be used near an open flame, a lighted cigarette or some devices (e.g. hair dryers).

Precautions for use:
In absence of data, the use of CURANAIL is not recommended for patients under 18 years old

4.5 Interaction with other medicinal products and other forms of interaction

The existence of clinically significant interactions is not suggested by current available data.

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 (see section 5.3); 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

Not relevant.

4.8 Undesirable effects

Adverse drug reactions were rare in clinical trials.

System Organ Class	Frequency	Adverse drug reaction
Immune system disorders	Unknown frequency*	Hypersensitivity (systemic allergic reaction)*
Skin and subcutaneous tissue disorders	Rare (≥1/10 000, <1/1000)	Nail disorder, nail discoloration, onychoclasis (broken nails), onychorrhexis (brittle nails)
	Very rare (<1/10 000)	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 after topical application of CURANAIL.
In case of accidental ingestion, appropriate symptomatic measures must be taken.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: OTHER ANTIFUNGALS FOR TOPICAL USE, ATC code:D01AE16

CURANAIL is a topical antifungal. The active ingredient, amorolfine, a morpholine derivative, belongs to a novel chemical class of antifungals. The fungistatic and fungicidal effects are mediated through impairment of the fungal cell membrane and mainly affect sterol biosynthesis.
The ergosterol content is reduced. Accumulation of atypical sterols results in morphological modifications of the cell membranes and organelles, inducing lysis of the fungal cell.

Amorolfine has a broad antifungal spectrum. It is highly effective against the usual and occasional causative agents of onychomycosis:

- Yeasts:
  - *Candida albicans* and other species of Candida.
- Dermatophytes:
  - *Trichophyton rubrum*, *Trichophyton interdigitale* and *Trichphyton mentagrophytes*, other species of Trichophyton,
  - *Epidermophyton floccosum*,
  - Microsporum.
- Moulds:
  - Scopulariopsis.
- Dematiacea (black fungi):
  - Hendersonula, Alternaria, Cladosporium.
- Less sensitive species:
  - Aspergillus, Fusarium, mucorales.

5.2 Pharmacokinetic properties

Amorolfine, in nail lacquer form, penetrates and diffuses through the nail plate and is thus able to eradicate poorly accessible fungi in the nail bed.

The systemic absorption of the active ingredient is negligible. Plasma concentrations remain lower than the limit of detection, even after one year of use.

5.3 Preclinical safety data

Oral thirteen-week studies have been performed with up to 60 mg / kg bw / day or 26-week studies with a dosage of up to 40 mg / kg bw / day in rats and dogs. Keratodermia and dermatitis like lesions of the skin, hyperkeratosis of mucous membrane and the transition skin/mucous membrane have been observed.

Reproductive toxicology studies showed evidence of teratogenicity, embryotoxicity and foetotoxicity in laboratory animals but these effects were observed at exposure far exceeding human exposure indicating no anticipated risk for pregnant women.

Amorolfine potential genotoxicity has been tested in vitro and in vivo. No genotoxic potential has been observed.

No carcinogenicity studies have been conducted.

Topical administration of amorolfine nail lacquer in animals has shown dermal toxicity under occlusive conditions. Amorolfine nail lacquer did not induce sensitisation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ammonio methacrylate copolymer type A (EUDRAGIT RL100)
Triacetin
Butyl acetate
Ethyl acetate
Ethanol anhydrous.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.
Shelf life after first opening: 6 months

6.4 Special precautions for storage

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
2.5 ml-glass bottle with accessories (30 nail files, 30 cleaning swabs, 30 applicators).
or
Amber glass type III bottle with screw thread and plastic screw closure with integretated applicator.
1.25 ml or 2.5 ml – glass bottle with accessories (nail files, cleaning swabs, applicator)
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special 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

PA22743/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th March 2012
Date of last renewal: 27th August 2014

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

10 DATE OF REVISION OF THE TEXT

February 2023