

APPROVED PACKAGE INSERT

SCHEDULING STATUS:

S1

PROPRIETARY NAME (and dosage form):**LOCERYL® 5 % Nail Lacquer****COMPOSITION:**

The active ingredient is amorolfine.

The nail lacquer contains 50 mg/1 ml.

PHARMACOLOGICAL CLASSIFICATION:

Category A: 13.9.2 - Fungicides

PHARMACOLOGICAL ACTION:

Amorolfine has both *in vitro* fungicidal and fungistatic properties 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 has a broad spectrum of action *in vitro* against:

yeasts: **Candida, Malassezia or Pityrosporum, Cryptococcus*

dermatophytes: **Trichophyton, *Microsporum, *Epidermophyton*

moulds: **Hendersonula, *Alternaria, *Scopulariopsis, Scytalidium*

dematiacea: **Cladosporium, Fonsecaea, Wangiella*

[* in onychomycosis]

dimorphic fungi: *Coccidioides immitis, Histoplasma capsulatum, Sporothrix schenckii*

In oral studies at high doses in animals, Amorolfine showed some additive effect *in vitro and in vivo* with several antifungals, including ketoconazole, itraconazole, terbinafine and griseofulvin, against dermatophytes.

With the exception of *Actinomyces*, bacteria are not sensitive to amorolfine.

Pharmacokinetics:

Amorolfine from the nail lacquer penetrates and diffuses through the nail plate and effective concentrations accumulate in the nail bed where access to fungi is critical. Systemic absorption of the active ingredient is very low with this type of application. Following prolonged topical use of amorolfine nail lacquer there is no indication of drug accumulation in the body.

INDICATIONS:

Onychomycoses caused by dermatophytes, yeasts and moulds.

Only little experience is available in cases where the nail matrix was involved.

CONTRA-INDICATIONS:

Patients who have shown hypersensitivity to the treatment must not reuse LOCERYL 5 % Nail Lacquer. No experience exists with pregnancy and nursing and the use of LOCERYL 5 % Nail Lacquer should therefore be avoided during pregnancy and lactation.

Owing to a lack of clinical experience to date, children should not be treated with LOCERYL 5 % Nail Lacquer.

WARNINGS:

Use of cosmetic lacquers or artificial nails should be avoided during treatment with LOCERYL 5 % Nail Lacquer.

INTERACTIONS:

See (DOSAGE AND DIRECTIONS FOR USE).

PREGNANCY AND LACTATION:

In view of the extremely low systemic exposure to amorolfine after use of the nail lacquer a foetal risk in humans appears to be negligible.

DOSAGE AND DIRECTIONS FOR USE:***Onychomycoses***

Nail Lacquer: To be applied to affected finger or toe nails once or twice weekly.

The patient should apply the nail lacquer as follows:

1. Before the first application of LOCERYL 5 % Nail Lacquer, it is essential that the affected areas of nail (particularly the nail surfaces) should be filed down as thoroughly as possible using a disposable nail file supplied. The surface of the nail should then be cleansed and degreased using an alcohol soaked swab (as supplied).

Before repeating application of LOCERYL 5 % Nail Lacquer, the affected nails should be filed down again as required, and must at all times first be cleansed with an alcohol soaked swab to remove any remaining lacquer.

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

2. With the applicator supplied, apply the nail lacquer to the entire surface of the affected nails and allow it to dry for approximately 3-5 minutes.

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

After use, clean the applicator with the same pre-soaked swab used before for nail cleansing. **Keep the bottle tightly closed.**

3. When working with organic solvents (thinners, white spirit, etc.) wear impermeable gloves in order to protect the LOCERYL 5 % 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 duration of treatment depends essentially on intensity and localisation of the infection and on growth rate of the nails, but in general, it is six months for fingernails and nine to twelve months for toe nails.

Clinical experience indicates that cure is achieved after six months in approximately 50 % of distal onychomycosis cases in which less than 80 % of the nail surface was affected. Mycological cure was achieved in 60-80 % of cases.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

System Organ Class	Frequency	Adverse drug reaction
Skin and subcutaneous tissue disorders	Frequent	Nail disorder, nail discolouration, broken nails, brittle nails. However, these reactions can also be linked to the onychomycosis itself.
	Less frequent	Skin burning sensation, contact dermatitis

Special Precautions:

Owing to the lack of clinical experience available to date, children - particularly young children and infants - should not be treated with LOCERYL 5 % Nail Lacquer.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Should LOCERYL 5 % Nail Lacquer be ingested, treatment should be symptomatic and supportive.

IDENTIFICATION:

LOCERYL 5 % Nail Lacquer: Colourless to almost colourless clear liquid.

PRESENTATION:

LOCERYL 5 % Nail Lacquer 5 ml and 2,5 ml

Supplied with:

1 Applicator attached to the cap

30 Disposable nail files

30 cleansing swabs, impregnated with 70 % isopropyl alcohol in foil packs.

STORAGE INSTRUCTIONS:

Protect from heat. Store below 30 °C. KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER:

27/13.9.2/0163

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF**REGISTRATION:**

Galderma Laboratories South Africa (Pty) Ltd

17 Muswell Road South

Bryanston

2021

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Directions for use

1. File the affected nails, especially the diseased parts of the nail surface, to eliminate as much as possible of the diseased nail and the fungus affecting it.

Caution: Use only the files in the treatment kit. Never file a healthy nail with a file used for diseased nails, otherwise you may spread the infection. Fungal infections are contagious; to prevent the spread of infection, take care that no other person uses the files from your kit.



2. Using one of the pre-soaked pads provided, wipe the entire surface of the affected nail(s). Take care to remove any previous coat of medicated nail lacquer



3. Dip the applicator into the bottle of medicated nail lacquer. The lacquer must not be wiped off the applicator on the edge of the bottle before it is applied.



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



5. Let the treated nail(s) dry for approximately three to five minutes.



6. The applicator provided is re-usable. However, it is important to clean it thoroughly after completing each treatment procedure, using the same pad you used for nail cleansing. Avoid touching newly treated nails with the pad.



7. Close the nail lacquer bottle tightly and throw away the used pad.

The medicated nail lacquer provided is not affected by soap and water, so you may wash your hands and feet in the normal way. However, if you handle solvents such as white spirit and paint thinner, you must wear rubber gloves, otherwise the nail lacquer will dissolve.

Every step of the treatment procedure is important. For a successful cure you must repeat each of the steps every time you treat your nails.

These measures and precautions may appear fussy; however, they are indispensable because they speed up healing and prevent healthy nails from becoming infected.

Remember: Successful treatment depends on your patience and perseverance.