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Certification Statement

We certify that the final electronic form of this material is in accordance with the regulations set forth by the health authority for the country of this document, and is a fair and truthful presentation of the facts about the product.

Role	Signature
Prasad Rahate - Regulatory Approval (prasad.rahate@galderma.com)	Meaning: As the Regulatory Approver, I approve this document for use. Date: 30-Jan-2025 05:16:00 GMT+0000

LOCERYL®

5% W/V AMOROLFINE MEDICATED NAIL LACQUER

ANTI-FUNGAL NAIL TREATMENT

COMPOSITION

Loceryl Nail Lacquer contains 5% w/v amorolfine (as hydrochloride) as the active ingredient in an ethanol-based nail lacquer containing Ammonio methacrylate copolymer, glycerol triacetate, butyl acetate, ethyl acetate and ethanol absolute.

PHARMACOLOGICAL PROPERTIES

Loceryl Nail Lacquer is a topical antifungal. The active substance, amorolfine, belongs to a new class of antifungal substances. Its fungicidal and fungistatic effect is based on an alteration of the fungal cell membranes targeted primarily on sterol biosynthesis. The ergosterol content is reduced, and at the same time unusual, sterically nonplanar sterols accumulate.

Amorolfine has a broad antifungal spectrum in vitro. It is effective against:

Dermatophytes: *Trichophyton, Microsporum, Epidermophyton*

Yeasts: *Candida*

Moulds: *Alternaria, Scopulariopsis, Hendersonula*

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

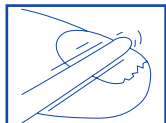
Pharmacokinetics: Amorolfine from the nail lacquer penetrates into and diffuses through the nail plate and is thus able to eradicate poorly accessible fungi in the nail bed. Systemic absorption of the active ingredient is very low with this kind of application, since the drug plasma concentrations remains below the sensitivity limit of the analytical assay even after one year of use.

INDICATIONS AND USAGE

Loceryl Nail Lacquer is indicated in the topical treatment of nail fungal infections (onychomycosis) caused by dermatophytes, yeasts and moulds.

DOSAGE AND ADMINISTRATION

Apply Loceryl Nail Lacquer to the affected nails at a dosage of 1 to 2 applications weekly. When applying the varnish carefully comply with the following recommendations.



1. Before first applying **Loceryl nail lacquer**, carefully clean the nails and using a nail file, file the affected area of the nail (particularly the surface of the nail) as completely as possible. Be careful not to file the peri-ungual skin.

CAUTION: Nail files used on an infected nail must **not** be used on healthy nails.



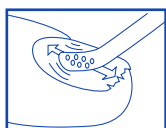
2. Clean the surface of the infected nail with a cleaning pad.

3. Repeat steps 1 & 2 for each infected nail.



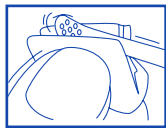
4. Dip the spatula attached to the cap into the lacquer. Do not wipe it on the edge of the bottle.

Note: the spatula provides a measured dose of **LOCERYL**

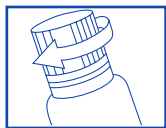


5. Using the spatula, paint **Loceryl Nail Lacquer** over the entire surface of the infected nail.

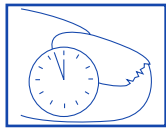
6. Repeat steps 4 & 5 for each infected nail.



7. When you have finished treating all of your infected nails, clean the spatula and the neck of the bottle with the same cleaning pad that was used for nail cleansing.



8. Close the bottle tightly immediately after use.



9. Allow time for the nails to dry (3 to 5 minutes).

NOTE: Follow these steps each time you use **LOCERYL**.

When working with organic solvents (thinners, white spirit, etc) wear impermeable gloves in order to protect the **LOCERYL** 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 the localization of the infection and on the growth rate of nails. In general, it is 6 months for fingernails and 9 to 12 months for toe nails.

If there is no improvement, or only small improvement after 6 to 12 months of treatment, see your healthcare professional

CONTRA-INDICATIONS

Loceryl Nail Lacquer must not be reused by patients who have shown hypersensitivity to any ingredient of the product.

SIDE EFFECTS

In exceptional cases, a slight, transient periungual skin burning sensation was observed after the application of the nail lacquer.

In rare cases, nail disorder (nail discolouration, brittle or broken nails) have been reported with the use of amorolfine 5% nail lacquer. However, these reactions can also be linked to the onychomycosis itself.

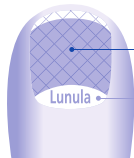
Hypersensitivity (systemic allergic reaction), contact dermatitis, erythema (redness), pruritus (itching), urticaria (hives) and blisters have also been reported with the use of the nail lacquer.

WARNINGS AND PRECAUTIONS

General: Nail files for affected nails must not be reused on healthy nails. Use of cosmetic lacquer or artificial nails should be avoided during treatment. Avoid contact of the lacquer with eyes, ears and mucous membranes. The lacquer should not be applied on the skin around the nail.

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.



✓ If fungal nail infection here: Suitable for Loceryl® treatment

● If fungal nail infection here: Loceryl® should not be used alone, talk to your healthcare professional

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 lacquer carefully using a nail lacquer remover solution and do not reapply.

Interactions with other medicinal products and other forms of interactions

No interaction studies have been performed.

Pediatric Use: Owing to the lack of clinical experience available to date, children under 12 years of age should not be treated with Loceryl.

PREGNANCY AND LACTATION

Exposure of pregnant rabbits to high systemic doses of amorolfine resulted in a slight increase of embryonic resorption (embryotoxicity). In view of the extremely low systemic exposure to amorolfine after the use of the lacquer, a fetal risk in humans appears to be negligible. However, as no clinical experience exists with pregnancy and nursing, the use of Loceryl should be avoided during pregnancy and lactation.

OVERDOSAGE

Overdosage is not expected to result in any clinical problem.

Accidental Oral Ingestion

Loceryl is for topical use. In case of accidental oral ingestion, seek medical advice. Appropriate symptomatic measures should be taken if needed.

SHELF-LIFE

This medicine should be not used after the expiry date (Exp. Date) shown on the pack.

STORAGE

Store below 30°C.

Loceryl Nail Lacquer must be stored protected from heat. Keep out of reach of children.

CONTAINER

Nail lacquer (5%) 1.25ml, 2.5ml and 5ml. Not all sizes may be marketed. Packs also contain 30 cleaning pads saturated with 70% isopropyl alcohol in foil packets, and 30 disposable nail files. Galderma International-France

Manufactured by:
Laboratoires Galderma, ZI-Montdésir
74540 Alby-sur-Chéran, France

Date of revision of the leaflet: June 2018

Galderma Laboratories

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GALDERMA
EST 1981

Printing Colors

PMS BLUE 072U

GRADIENT LOCERYL

DIELINES

HONG KONG

羅霉樂抗癬甲油

使用本藥物前請詳細閱讀以下說明，如有任何疑問，請諮詢醫生或藥劑師。

成份

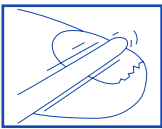
羅霉樂抗癬甲油含活性成份5%(w/v) amorolfine (作為鹽酸), 其他成份包括 Ammonio methacrylate copolymer, glycerol triacetate, butyl acetate, ethyl acetate and ethanol absolute.

適應症

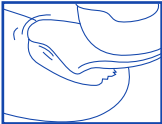
羅霉樂抗癬甲油屬於外用抗真菌藥物,適用於治療趾/指甲真菌感染(灰甲/甲癬)。 包括被皮癬菌, 酵母菌或黴菌感染的手甲及腳甲。

劑量與用法

每星期一至兩次將甲油塗於患甲上。 應當遵守以下的建議使用：

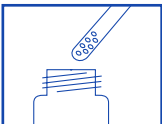


1. 塗上甲油前，仔細清洗指甲，可使用甲銼銼平整個受影響的位置（特別是受影響的指甲表面）。請小心不要弄傷指甲周邊的皮膚。
注意：已使用的甲銼請勿重覆使用在健康的指甲上。



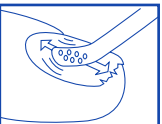
2. 用酒精棉清潔患甲表面。

3. 於每隻患甲上重複步驟1和2。



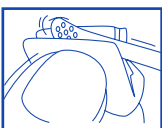
4. 用塗抹棒取出甲油。
取出時不要擦拭塗抹棒於瓶子的邊緣。

注意：塗抹棒能取出適當劑量的甲油

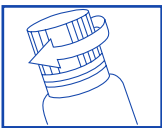


5. 用塗抹棒將甲油塗在整個患甲表面。

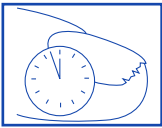
6. 於每隻患甲上重複步驟4和5。



7. 當完成以上步驟，可使用剛使用過的酒精棉清潔塗抹棒和瓶子的頸部。



8. 塗藥後立即把蓋蓋上及關緊。



9. 等待甲油乾透（3~5分鐘）。

注意：每次使用羅霉樂請遵循這些步驟。

若有需要使用有機溶劑（稀釋劑、白酒等），為免溶掉甲油，請穿上防滲手套。

患者應持續治療，直到健康的指甲重新長出，而受感染的位置已獲得治愈。治療時間取決於指甲受感染的嚴重程度、位置及生長速度。在一般情況下，手指甲感染需治療6個月，而腳指甲需9至12個月。如果6至12個月後仍沒有改善，或只有小的改善，請諮詢醫生意見。

禁忌

對本藥的成份呈過敏反應者不宜再使用。

不良反應

使用本藥後，患者的指甲及周邊皮膚可能會出現輕度、短暫灼熱感。

有極少數病人在使用藥物後出現指甲變色、脆弱或斷甲。

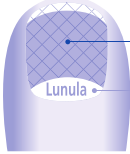
但是這些情況都屬於灰甲/甲癬的徵狀。

有報告顯示使用本藥可能會引致過敏（系統性過敏反應,接觸性皮炎,紅斑（發紅）,瘙癢（瘙癢）,蕁麻疹（麻疹）和水泡。

警告及注意事項

請勿把用於患甲的指甲銼刀，再用於健康的指甲上。治療期間應避免使用化妝品類的指甲油劑及人工指甲。避免把本藥接觸眼、耳及黏膜處。不要把藥塗於指甲的周邊皮膚。

如患者因為其他病因導致指甲病變，例如外週循環障礙、糖尿病和免疫抑制病患，請諮詢醫生意見。



✓ 若這範圍受感染，適合使用羅霉樂治療

X 若這範圍受感染，不應單獨使用羅霉樂，請諮詢醫生意見。

若使用本藥後出現過敏反應，應停止使用，並諮詢醫生意見。可使用指甲油清除液徹底抹去本藥，並且不要重新塗抹。

若患者指甲出現營養不良或已損壞的情況，也應諮詢醫生意見。此藥物未有與其他藥物產生相互作用之報告。由於缺乏治療兒童的研究報告，12歲或以下人士不宜使用。授乳及懷孕婦女，請勿使用本藥品。

不可吞食。只供外用。

用藥過量

預期用藥過量不會導致任何臨床問題。

意外服食

本藥品只供外用。若意外服食，立即尋求醫生意見。並採取適當的治療。

使用期限

包裝上印刷的有效期限過後不應繼續使用。

保存方法

避免高溫，請存放於30° C以下。置於遠離兒童的地方。

包裝

羅霉樂抗癬甲油分別有1.25, 2.5 及5毫升裝。
盒內附有30小包消毒酒精藥棉(含70%酒精)及30片即棄式甲銼。

生產商：

高德美大藥廠
法國製造

GALDERMA

Galderma Laboratories

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