

DISCLAIMER

All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akom's Customer Service department at 800.932.5676.

Ciclopirox Topical Solution, 8% (Nail Lacquer)

Rx Only

PATIENT INFORMATION

Patients should have detailed instructions regarding the use of Ciclopirox Topical Solution, 8% (Nail Lacquer) as a component of a comprehensive management program for onychomycosis in order to achieve maximum benefit with the use of this product. Discuss your treatment plan with your health care professional for regular removal of the unattached, infected nail.

Call your doctor for medical advice about side effects. You may report side effects to Hi-Tech Pharmacal Co., Inc. at 1-800-262-9010 or FDA at 1-800-FDA-1088.

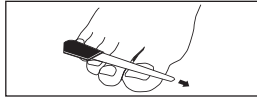
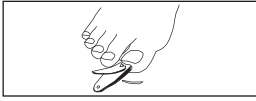
Before using this medication, tell your doctor if you:

- Are pregnant or nursing
- Are an insulin dependent diabetic or have diabetic neuropathy
- Have a history of immunosuppression
- Are immunocompromised (e.g., received an organ transplant, etc.)
- Require medication to control epilepsy
- Use or require topical corticosteroids on a repeated monthly basis
- Use steroid inhalers on a regular basis

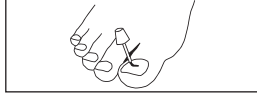
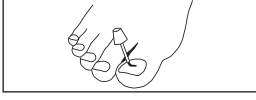
Patient Information:

- Use Ciclopirox Topical Solution, 8% (Nail Lacquer) as directed by your health care professional.
- Ciclopirox Topical Solution, 8% (Nail Lacquer) is for external use only.
- Contact with skin other than skin immediately surrounding the treated nail(s) should be avoided.
- Avoid contact with the eyes and mucous membranes.
- Removal of the unattached, infected nail, as frequently as monthly, by your health care professional is needed with use of this medication to obtain maximal benefit with use of this product. If you have diabetes or problems with numbness in your toes or fingers, talk to your health care provider before trimming your nails or removing any nail material.
- Inform your health care professional if the area of application shows signs of increased irritation (redness, itching, burning, blistering, swelling, oozing).
- Up to 48 weeks of daily applications with Ciclopirox Topical Solution, 8% (Nail Lacquer) and professional removal, as frequently as monthly, of the unattached, infected nail are considered the full treatment time to achieve a clear or almost clear nail (defined as 10% or less residual nail involvement). Six months of therapy with professional removal of the unattached, infected nail may be required before initial improvement of symptoms is noticed.
- A completely clear nail may not be achieved with use of this medication. In clinical studies less than 12% of patients were able to achieve either a clear or almost clear toenail.
- Do not use nail polish or other nail cosmetic products on the treated nails.
- Avoid use near heat or open flame, because product is flammable.

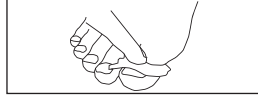
PATIENT INSTRUCTIONS



1. Before starting treatment, remove any loose nail or nail material using nail clippers or nail files. If you have diabetes or problems with numbness in your toes or fingers, talk to your health care provider before trimming your nails or removing any nail material.

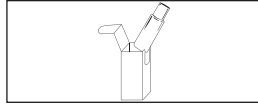


2. Apply Ciclopirox Topical Solution, 8% (Nail Lacquer) once daily (preferably at bedtime) to all affected nails with the applicator brush provided. Apply the lacquer evenly over the entire nail. Where possible, nail lacquer should also be applied to the underside of the nail and to the skin beneath it. Allow lacquer to dry (approximately 30 seconds) before putting on socks or stockings. After applying medication, wait 8 hours before taking a bath or shower.
3. Apply Ciclopirox Topical Solution, 8% (Nail Lacquer) daily over the previous coat.
4. Once a week, remove the Ciclopirox Topical Solution, 8% (Nail Lacquer) with alcohol. Remove as much as possible of the damaged nail using scissors, nail clippers, or nail files.
5. Repeat process (steps 2 through 4).



Please Note:

1. To prevent screw cap from sticking to the bottle, do not allow solution to get into the bottle threads.
2. To prevent the solution from drying out, bottle should be closed tightly after every use.
3. To protect from light, replace bottle into carton after each use.



Manufactured by:
Hi-Tech Pharmacal Co., Inc.
Amityville, NY 11701
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