

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use KERYDIN safely and effectively. See full prescribing information for KERYDIN.

**KERYDIN® (tavaborole) topical solution, 5%**  
Initial U.S. Approval: 2014

-----**INDICATIONS AND USAGE**-----  
KERYDIN is an oxaborole antifungal indicated for the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*. (1)

-----**DOSAGE AND ADMINISTRATION**-----  
• Apply KERYDIN to affected toenails once daily for 48 weeks. (2)  
• KERYDIN should be applied to the entire toenail surface and under the tip of each toenail being treated. (2)  
• For topical use only. (2)  
• Not for oral, ophthalmic, or intravaginal use. (2)

-----**DOSAGE FORMS AND STRENGTHS**-----  
Solution, 5%. (3)

-----**CONTRAINDICATIONS**-----  
None. (4)

-----**ADVERSE REACTIONS**-----  
Common adverse reactions occurring in  $\geq 1\%$  in subjects treated with KERYDIN included application site exfoliation, ingrown toenail, application site erythema, and application site dermatitis. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Anacor Pharmaceuticals at 1-844-4ANACOR [1-844-426-2267] or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 03/2015

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## General information about the safe and effective use of KERYDIN

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about KERYDIN that is written for health professionals. Do not use KERYDIN for a condition for which it was not prescribed. Do not give KERYDIN to other people, even if they have the same symptoms that you have. It may harm them.

## What are the ingredients in KERYDIN?

**Active ingredient:** tavaborole

**Inactive ingredients:** alcohol, propylene glycol, and edetate calcium disodium

## Instructions for Use

### KERYDIN® (ker' i din)

#### (tavaborole) Topical Solution, 5%

**Important information: KERYDIN is for use on toenails only.** Do not use KERYDIN in your mouth, eyes, or vagina.

Read the Instructions for Use that comes with KERYDIN before you start using it. Talk to your healthcare provider if you have any questions.

## How to apply KERYDIN:

Your toenails should be clean and dry before you apply KERYDIN.

**Step 1:** Before you apply KERYDIN to your affected toenail for the first time, remove the cap from the KERYDIN bottle. (See **Figure A**) Throw away the cap.

**Step 2:** Remove the wrapping from the dropper that comes with KERYDIN. Insert the dropper into the KERYDIN bottle. (See **Figure B**)

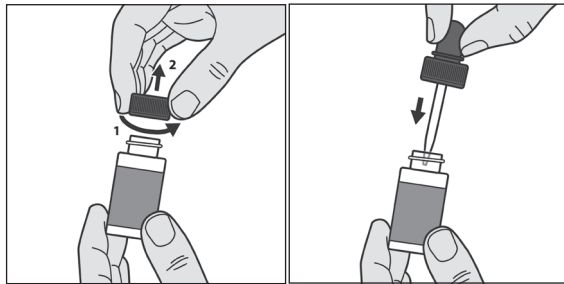


Figure A

Figure B

Only apply KERYDIN using the provided dropper. Do not use the dropper for any other purpose.

**Step 3:** With the dropper inserted into the KERYDIN, squeeze the bulb and then release the bulb to draw KERYDIN into the dropper.

**Step 4:** Remove the dropper from the bottle and hold the dropper tip over your affected toenail.

**Step 5:** Slowly squeeze the bulb to apply KERYDIN to your toenail. Apply enough solution to completely cover your toenail. You may need to use more than one drop. (See **Figure C**)

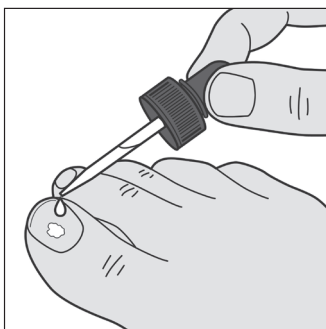


Figure C

**Step 6:** Use the dropper tip to gently spread KERYDIN to cover the entire toenail up to the edges of the toenail. (See **Figure D**)

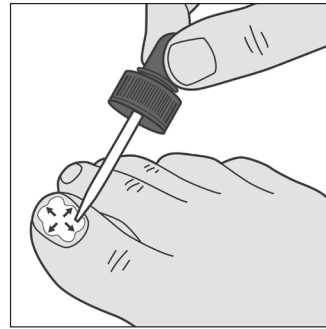


Figure D

**Step 7:** In addition to the top of the toenail, also apply KERYDIN under the tip of the toenail. Use the dropper tip to gently spread KERYDIN under the entire tip of the toenail. (See **Figures E and F**)

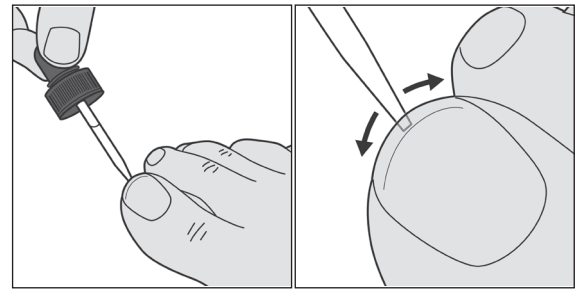


Figure E

Figure F

**Step 8:** Repeat Steps 3 to 7 to apply KERYDIN to each affected toenail.

**Step 9:** Let the KERYDIN dry completely. This may take a couple of minutes.

If KERYDIN comes in contact with surrounding skin, use a tissue to wipe any excess solution from the surrounding skin. **Do not wipe KERYDIN off of your toenails.**

**Step 10:** After applying KERYDIN to your toenails, insert the dropper back into the bottle and screw it on tightly.

**Step 11:** Wash your hands with soap and water after applying KERYDIN.

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

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