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
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 ≥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 Pfizer, Inc. at 1-800-438-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

Revised: 08/2018

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Animal Data

Data

8.5 Pregnancy

KERYDIN is systemically absorbed. The lack of clinical data during lactation makes it difficult to estimate the potential impact of tavaborole on the nursing infant. Because the potential for serious adverse reactions in nursing infants outweighs any potential benefit, KERYDIN is not recommended for use in nursing women while they are breastfeeding.

There is no information available on the presence of tavaborole in human milk, or its effect on milk production after topical application of KERYDIN to women who are breastfeeding. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In two oral trials, 701 subjects were treated with KERYDIN. The most commonly reported adverse reactions are listed below (Table 1).

Table 1: Adverse Reactions Occurring in ≤1% of KERYDIN Topical Solution, 5%-Treated Subjects and at a Greater Frequency Than Placebo

<table>
<thead>
<tr>
<th>Efficacy Variable</th>
<th>Complete or Almost Complete Cureb</th>
<th>Ingrown toenail 20 (2.5%)</th>
<th>1 (0.3%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>c. Mycologic cure defined as negative KOH and negative culture.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The safety and efficacy of KERYDIN were established in patients 6 years of age and older. Use of KERYDIN in these age groups is supported by evidence from adequate and well-controlled studies of KERYDIN in adults with additional data from an open-label pharmacokinetics study of tavaborole in subjects 12 years to less than 17 years old (see Clinical Pharmacology). There are no available data on KERYDIN use in pregnant women to inform a drug and effect relationship to drug product exposure. 

Hypersensitivity: contact allergy

8. USE IN SPECIFIC POPULATIONS

18.3 Pharmacokinetics

During an oral pharmacokinetics study of tavaborole in subjects 12 years to 17 years of age, the mean C max was 3.5 ± 2.3 ng/mL (n=21 with measurable concentrations, range 0.618-10.2 ng/mL, 82% male, 84% white, participated in these two trials. Efficacy assessments were made at 25 weeks following a 48-week treatment period. The Combo Care regimen endpoint included negative mycologic (negative KOH wet mount and negative fungal culture) and Complete Clear nail (clear nail appearance as evidenced by normal lunule position, and no subungual hyperkeratosis). Efficacy results from the two trials were analyzed separately.

Table 2: Efficacy Outcomes

17. PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patient Information and Instructions for Use).

The patient should be told the following:

- The impact of nail polish or other cosmetic nail products on the efficacy of KERYDIN has not been evaluated.

- KERYDIN is flammable. AVOID USE NEAR HEAT OR OPEN FLAME.

- Keep bottle tightly closed. KEEP OUT OF REACH OF CHILDREN.

- Do not use near heat or open flame.

- Keep bottle tightly closed. Keep out of reach of children.

- Apply KERYDIN to affected toenails once daily for 48 weeks.

- Store at 20°C–25°C (68°F–77°F); excursions permitted to 15°C–30°C (59°F–86°F) (see USP Controlled Room Temperature).

- Keep bottle tightly closed. Keep out of reach of children.

- Store at 20°C–25°C (68°F–77°F); excursions permitted to 15°C–30°C (59°F–86°F) (see USP Controlled Room Temperature).

- CAUTION: Flammable. Keep away from heat and flame.

- Distributed by:

- PharmaDerm®

- A Division of Forge Pharmaceuticals Inc.

- KERYDIN® is a trademark of Anacor Pharmaceuticals, Inc. © 2015 Anacor Pharmaceuticals, Inc.

- U.S. Patent Nos. 7,767,657 and 7,582,621

- KERYDIN® is for topical use only and not for oral, ophthalmic, or intravaginal use.

- The safety and efficacy of KERYDIN were established in patients 6 years of age and older. Use of KERYDIN in these age groups is supported by evidence from adequate and well-controlled studies of KERYDIN in adults with additional data from an open-label pharmacokinetics study of tavaborole in subjects 12 years to less than 17 years old (see Clinical Pharmacology). There are no available data on KERYDIN use in pregnant women to inform a drug and effect relationship to drug product exposure.

- Hypersensitivity: contact allergy.
**PATIENT INFORMATION**

**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.

**What is KERYDIN?**

KERYDIN is a prescription medicine used to treat fungal infections of the toenails. It is not known if KERYDIN is safe and effective in children less than 6 years of age.

**Before using KERYDIN,** tell your healthcare provider about all of your medical conditions, including if you:
- are pregnant or plan to become pregnant. It is not known if KERYDIN can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if KERYDIN passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during your treatment with KERYDIN.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**How should I use KERYDIN?**

See the “Instructions for Use” at the end of this Patient Information for detailed information about the right way to use KERYDIN.

**Use KERYDIN exactly as your healthcare provider tells you to use it.**

**Apply KERYDIN to your affected toenails 1 time each day.**

**KERYDIN is used for 48 weeks.**

- **It is not known if the use of nail polish or other cosmetic nail products (such as gel nails or acrylic nails) will affect how KERYDIN works.**

**What should I avoid while using KERYDIN?**

- **KERYDIN is flammable.** Avoid heat and flame while applying KERYDIN to your toenail.

**What are the possible side effects of KERYDIN?**

The most common side effects of KERYDIN include: skin peeling, ingrown toenail, redness, itching, and swelling.

KERYDIN may cause irritation at or near the application site. Tell your healthcare provider if you develop irritation at the application site that does not go away. These are not all of the possible side effects of KERYDIN.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store KERYDIN?**

- Store KERYDIN at room temperature, between 68°F to 77°F (20°C to 25°C).
- KERYDIN is flammable. Keep away from heat and flame.
- Keep the bottle tightly closed.
- Safely throw away KERYDIN after 3 months of inserting the dropper.

**Keep KERYDIN and all medicines out of the reach of children.**

**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. 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. You can ask your pharmacist or healthcare provider for information about KERYDIN that is written for health professionals.

**What are the ingredients in KERYDIN?**

**Active ingredient:** tavaborole

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

Manufactured for: Pfizer Labs, Division of Pfizer, Inc., NY, NY 10017
Distributed by: PharmaDerm®, a division of Fougera Pharmaceuticals, Inc., Melville, New York 11747 USA
For more information, call PharmaDerm®, a division of Fougera Pharmaceuticals, Inc., at 1-800-645-9833.

**This Patient Information has been approved by the U.S. Food and Drug Administration.**

**Revised August 2018**

**Instructions for Use**

**KERYDIN® (ker’i din)**
(tavaborole) topical solution, 5%

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)

**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 A**

**Figure B**

**Important information: KERYDIN is for use on toenails only.**

Do not use KERYDIN in your mouth, eyes, or vagina.

**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.

Avoid getting KERYDIN on skin that is not surrounding the treated toenail(s). 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 have been approved by the U.S. Food and Drug Administration. Manufactured for: Pfizer labs, Division of Pfizer Inc, NY, NY 10017 Distributed by: PharmaDerm®, a division of Fougera Pharmaceuticals, Inc., Melville, New York 11747 USA

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