

## FIRST TIME GENERIC APPROVAL

<b>Brand Name</b>	Kerydin®
<b>Generic Name</b>	tavaborole topical solution, 5%
<b>Drug Manufacturer</b>	ENCUBE

### New Drug Approval

#### TYPE OF CLINICAL UPDATE

First Time Generic Approval

#### FDA APPROVAL DATE

October 13, 2020

#### LAUNCH DATE

October 22, 2020

#### REVIEW DESIGNATION

Standard

#### TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 212215

#### DISPENSING RESTRICTIONS

Open Distribution

### Overview

#### INDICATION FOR USE

Tavaborole topical solution, 5% is an oxaborole antifungal indicated for the treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*.

#### MECHANISMS OF ACTION

It is an oxaborole antifungal. It inhibits fungal protein synthesis by inhibition of an aminoacyl-transfer ribonucleic acid (tRNA) synthetase (AARS).

#### DOSAGE FORM AND STRENGTH

Topical solution, 5%. Clear, colorless alcohol-based solution. Each milliliter of solution contains 43.5 mg (5% w/w) of tavaborole.

#### DOSE & ADMINISTRATION

Apply to affected toenails once daily for 48 weeks.

Should be applied to the entire toenail surface and under the tip of each toenail being treated.

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