

Monthly Usage of Efinaconazole 10% Solution in Two Phase 3 Randomized Trials: Is One 4-mL Bottle Enough for Proper Treatment?

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SYNOPSIS

- Topical therapies for onychomycosis require extended treatment durations, and incomplete or intermittent treatment can contribute to high rates of reinfection or relapse¹
- Excellent adherence to treatment is necessary to maximize efficacy,² and prescribing an adequate quantity of medication is essential for good adherence
- Efinaconazole 10% topical solution—an azole antifungal used to treat onychomycosis in patients aged 6 years and older—is available in 4- or 8-mL bottles
- In the absence of data on patient characteristics influencing the amount of efinaconazole needed, 87% of efinaconazole prescriptions in 2022 were written for one 4-mL bottle per month³

OBJECTIVES

- To determine monthly efinaconazole usage by baseline patient demographics and clinical characteristics

METHODS

- Two identical, double-blind, phase 3 studies (NCT01008033; NCT01007708) enrolled adult participants (18–70 years; N=1655) with mild-to-moderate distal lateral subungual onychomycosis affecting 20–50% of ≥1 great (target) toenail⁴
- Participants were randomized (3:1) to treatment with efinaconazole 10% solution or vehicle, self-applied once daily for 48 weeks
- Bottles of study product (10 mL) were weighed upon dispensation at each study visit (every 4 weeks) and upon return at the following visit
- Monthly efinaconazole use was analyzed post hoc based on the total number of affected toenails and percent involvement of the target toenail at baseline as well as body mass index (BMI) and sex

RESULTS

- At baseline, efinaconazole-treated participants in both studies (N=656 and 580) had on average over one-third involvement of their target toenails (36.2% and 36.7%) and 3.7–3.8 affected toenails⁴
- Among efinaconazole-treated participants with usage data for this analysis (n=1067), 85% had target toenail involvement of ≥25%, and over 55% had ≥4 affected toenails
- As expected, percent involvement of the target toenail, BMI, or sex did not significantly impact average monthly efinaconazole usage (Figure 1)
- Among participants with ≥2 affected toenails (90%), average monthly efinaconazole usage was equivalent to 1.10–1.59 4-mL bottles per month (Figure 2)
 - Only participants with one affected toenail used <4 mL of efinaconazole monthly
 - For patients with 6 affected toenails, one 4-mL bottle of efinaconazole would provide an average of 19 days of treatment

FIGURE 1. Monthly Efinaconazole Use by Baseline Severity at Target (Great) Toenail, BMI, and Sex

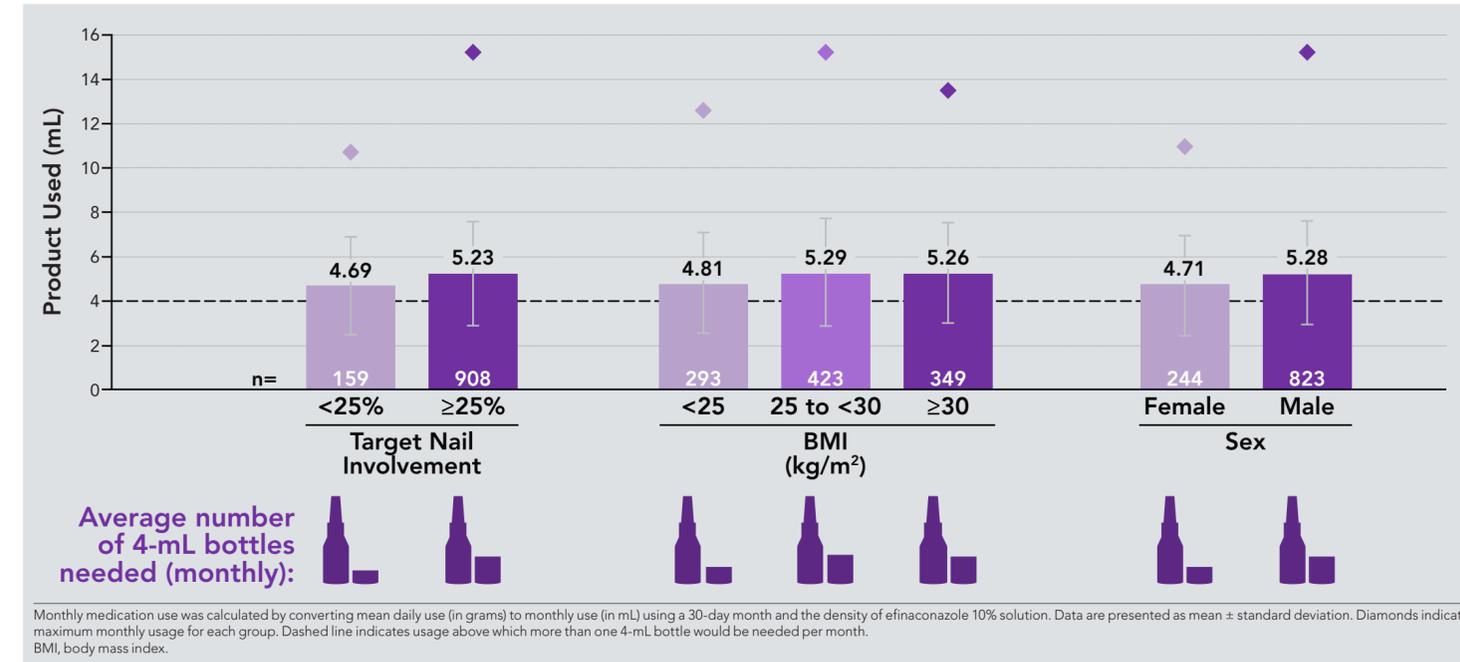
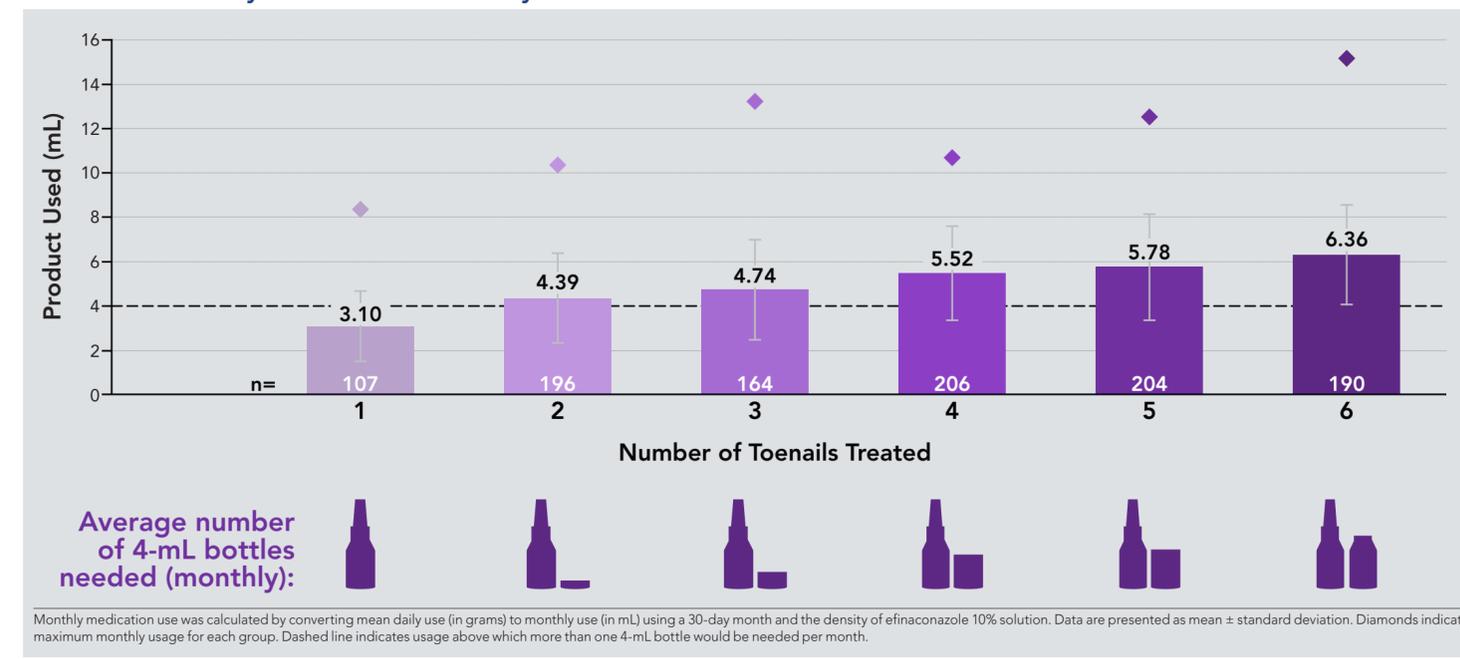


FIGURE 2. Monthly Efinaconazole Use by Number of Affected Toenails



CONCLUSIONS

- In this large sample of patients with onychomycosis, most had 2 or more affected toenails and used on average more than 4 mL of efinaconazole per month
- In contrast, almost 90% of patients in clinical practice are prescribed only one 4-mL bottle monthly, demonstrating a potential disconnect between product need and amount provided to patients
- Most patients with onychomycosis of ≥2 toenails may find that one 4-mL bottle of medication runs out in less than a month, leaving gaps in treatment until prescriptions can be refilled
 - This may prolong time to achieve clinical effects and increase the likelihood of relapse or reinfection¹
- Given that nail percent involvement, sex, and BMI do not affect medication usage, number of affected nails should be the major consideration when determining monthly efinaconazole quantity to prescribe
 - Clinicians should consider prescribing the larger 8-mL bottle of efinaconazole to patients with onychomycosis of more than one affected toenail

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AUTHOR DISCLOSURES

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