Safety, Pharmacokinetics, and Efficacy of Efinaconazole 10% Topical Solution for the Treatment of Onychomycosis in Pediatric Patients

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SYNOPSIS

- Onychomycosis—a chronic fungal nail infection—can occur in children, ranging in prevalence from 0.3%–5.5% worldwide.
- Onychomycosis has been reported to be responsible for approximately 15% of all nail dystrophy cases in children.
- Treatment of onychomycosis is challenging, and can require systemic antifungals for prolonged periods of time; however, parents and pediatricians are hesitant to use long-term systemic treatments in children.

METHODS

- This phase 4, multicenter, open-label study evaluated safety, pharmacokinetics (PK), and efficacy of efinaconazole 10% topical solution in pediatric patients with distal lateral subungual onychomycosis.
- Efinaconazole was administered once daily for 48 weeks, with a 4-week washout period.
- Treatment of onychomycosis is challenging, and can require systemic antifungals for prolonged periods of time; however, parents and pediatricians are hesitant to use long-term systemic treatments in children.

RESULTS

- The study population comprised 15 patients; 2 patients were not included (samples arrived thawed from facility [n=1] and statistical outlier [n=1]).
- The concentration-time profile for efinaconazole and the H3 metabolite was variably stable, with only minor fluctuations during the 24-hour dosing interval (Figure 1).
- Systemic exposure to efinaconazole was low (Table 2).
- Efinaconazole was not detected in blood samples collected on day 28 and 28 (29 and 28, respectively).
- The mean (SD) plasma concentration-time profiles for efinaconazole and the H3 metabolite are shown in Figure 1.

Pharmacokinetics

- The plasma exposure to efinaconazole was low (mean ± standard deviation: Cmax = 1.25 ± 0.25 ng/mL, AUC0-24 = 50.0 ± 25 ng·h/mL).
- Efinaconazole was not detected in blood samples collected on day 28 and 28 (29 and 28, respectively).

CONCLUSIONS

- Efinaconazole 10% topical solution administered once daily for 48 weeks is well tolerated in the pediatric population.
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