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Julia (efinaconazole) Topical Solution
Clinical Update

Clinical Update: Patient Population Altered- FDA Approves Ortho Dermatologics' Labeling for Julia (efinaconazole) Topical Solution, 10%, In Patients As Young As Six Years Old.
FDA approval date: April 26, 2020

Julia (efinaconazole) is a topical triazole antifungal for the treatment of onychomycosis of the toenails. Onychomycosis is a chronic fungal nail infection caused predominantly by dermatophyte fungi that typically occurs under the toenail, though fingernails may also be affected. The condition typically begins as a small white or yellow spot beneath the nail, and causes nail discoloration, thickening and/or distortion, pain, detachment of the nail from the nail bed and irregular surface changes. Once onychomycosis begins, it can persist indefinitely if not treated and may cause permanent nail damage.

The safety, pharmacokinetics and efficacy of Julia in patients ages six to 16 years old were evaluated in a multicenter, open-label, single-arm Phase 4 study that enrolled 62 patients with mild-to-severe onychomycosis. The primary objectives were to evaluate the safety of Julia over the 52 weeks of the study in pediatric subjects with at least mild onychomycosis of the toenails, as well as the pharmacokinetics of Julia at four weeks in pediatric subjects 12 to 16 years with moderate-to-severe onychomycosis of the toenails. Efficacy assessments included mycologic cure (fungus-free), complete cure (completely clear nails and fungus-free), and clinical efficacy (<10 percent toenail involvement).

In the study, Julia was shown to be well tolerated in the pediatric population. The most common treatment-related side effect was ingrown nails. The systemic exposure to Julia in this pediatric population was comparable to that previously reported in adults. The efficacy assessments showed that by week 52, 65 percent of patients achieved mycologic cure, with a 36.7 percent mycologic cure rate observed as early as week 12. A total of 40 percent of patients had complete cure by week 52, and half of patients achieved clinical efficacy by the study conclusion.