JUBLIA®
(efinaconazole)
Topical Solution 10%

FOR USE IN AGES 6 YEARS AND UP[1]

THE #1 PRESCRIBED BRAND FOR ONYCHOMYCOSIS[2]

JUBLIA WAS ASSESSED IN PEDIATRIC PATIENTS IN A PHASE 4 STUDY AND IN ADULTS IN TWO PHASE 3 STUDIES[3,4]

In two Phase 3 studies of adult patients, JUBLIA was proven effective to restore healthy fungus-free nails[3]*

Complete cure† rates at 52 weeks after 48 weeks of active treatment

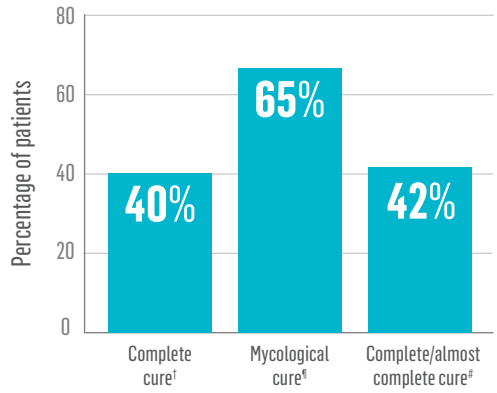
- 17.8% with JUBLIA (N=656) vs 3.3% with vehicle (N=214) in study 1; 15.2% (N=580) vs 5.5% (N=201), respectively, in study 2 (*P*<0.001 vs vehicle in both studies)

The most common adverse reactions (incidence ≥1%) were ingrown toenails, application site dermatitis, application site vesicles, and application site pain.[1]

In a Phase 4 study of pediatric patients (6 years and up), JUBLIA demonstrated:[1,4‡]

- **Favorable safety** (N=60), with ingrown toenail as the only treatment-related adverse event (3.3%)
- **Low systemic exposure** in pediatric patients (aged 12-16, n=15), which was consistent with findings in the Phase 3 adult population§
- **40% complete cure† rate at 52 weeks** (N=60)||

CURE RATES AT 52 WEEKS[4‡||]
(48 WEEKS ACTIVE TREATMENT)



*Phase 3 Study Design: In 2 identical, multicenter, randomized, parallel-group, double-blind, vehicle-controlled studies, patients with mild to moderate toenail distal lateral subungual onychomycosis (defined as 20%-50% clinical involvement of the target toenail, without dermatophytomas or matrix [lunula] involvement) were randomized to receive efinaconazole 10% solution or vehicle.[3]

†Complete cure defined as 0% involvement of the target nail in addition to mycological cure, defined as both negative fungal culture and negative KOH.[3,4]

‡Phase 4 Study Design: The safety and efficacy of JUBLIA were assessed in a Phase 4 multicenter, open-label, single-arm study of pediatric patients (6-16 years) with at least mild toenail distal lateral subungual onychomycosis (defined as ≥20% clinical involvement of the target toenail, without dermatophytomas or matrix [lunula] involvement) on at least one great toenail (N=60). The pharmacokinetics of JUBLIA were assessed in a subset of patients aged 12-16 years with ≥50% clinical involvement of both great toenails plus onychomycosis in ≥4 additional toenails (n=15).[4]

§Plasma concentrations in pediatric patients: C_{max} = 0.55 ± 0.38 ng/mL; AUC_{0-24} = 11.4 ± 7.68 h•ng/mL. Plasma concentrations in adult patients: C_{max} = 0.67 ± 0.37 ng/mL; AUC_{0-24} = 12.15 ± 6.91 h•ng/mL.[1]

||Derived from safety population with last observation carried forward (LOCF).

¶Mycological cure defined as negative fungal culture and a negative KOH examination of the target toenail.[4]

#Complete/almost complete cure: ≤5% clinical involvement of the target toenail, as well as mycological cure.[4]

INDICATION

JUBLIA® (efinaconazole) topical solution, 10%, is indicated for the topical treatment of onychomycosis (tinea unguium) of the toenail(s) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*.

IMPORTANT SAFETY INFORMATION

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

Please see additional Important Safety Information on next page and click here for full Prescribing Information.

THE #1 PRESCRIBED BRAND FOR ONYCHOMYCOSIS[2]

THE SAFETY AND EFFICACY OF JUBLIA WERE ESTABLISHED IN PEDIATRIC PATIENTS (6 YEARS AND OLDER) AND ADULTS IN PHASE 4 AND PHASE 3 STUDIES, RESPECTIVELY[1,3,4]

Small, water-soluble molecules with low keratin affinity help JUBLIA effectively reach infected nail beds[5-7]

Treats the source of infection, regardless of nail thickness or presence of nail polish[8]

Similar cure rates observed in patients with and without diabetes[9]

$0 CO-PAY*

1st Rx and Eligible Refills
for 4mL or 8mL sizes

Exclusively at Walgreens and other participating independent pharmacies for most eligible commercially insured patients

Or $65 for most eligible commercially insured patients whose insurance does not cover the drug†

*This offer is only valid for patients with commercial insurance and eligible uninsured patients. This offer is not valid for any person eligible for reimbursement of prescriptions, in whole or in part, by any federal, state, or other governmental programs, including, but not limited to, Medicare (including Medicare Advantage and Part A, B, and D plans), Medicaid, TRICARE, Veterans Administration or Department of Defense health coverage, CHAMPUS, the Puerto Rico Government Health Insurance Plan or any other federal or state health care programs. This offer is good only in the United States of America (including the District of Columbia, Puerto Rico and the U.S. Virgin Islands) at retail pharmacies owned and operated by Walgreen Co. (or its affiliates) and other participating independent retail pharmacies. This offer is not valid in Massachusetts or Minnesota or where otherwise prohibited, taxed, or otherwise restricted. Go to OrthoRxAccess.com for full eligibility terms and conditions.

†Insured not covered is defined as a patient who has commercial insurance but the drug is not covered on the formulary or has an NDC block, prior authorization, step edit or other restriction that has not been met.

IMPORTANT SAFETY INFORMATION

- Patients should be instructed to contact their health care professional if a reaction suggesting sensitivity or severe irritation occurs.
- The most common adverse reactions (incidence ≥1%) were (vs vehicle): ingrown toenail (2.3% vs 0.7%), application-site dermatitis (2.2% vs 0.2%), application-site vesicles (1.6% vs 0%), and application-site pain (1.1% vs 0.2%).
- JUBLIA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus, and should be used with caution in nursing women. The safety and effectiveness in pediatric patients below 6 years of age have not been established.

To report SUSPECTED ADVERSE REACTIONS, contact Ortho Dermatologics at 1-800-321-4576 or the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please see additional Important Safety Information on previous page and click here for full Prescribing Information.

References: 1. JUBLIA [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC. **2.** Toenail fungus market summary – TRx: April 2020. IQVIA. **3.** Elewski BE, Rich P, et al. Efinaconazole 10% solution in the treatment of toenail onychomycosis: two phase III multicenter, randomized, double-blind studies. *J Am Acad Dermatol.* 2013;68(4):600-608. **4.** Data on file. Bridgewater, NJ: Bausch Health US, LLC. **5.** Angelo T, Borgheti-Cardoso LN, Gelfuso GM, et al. Chemical and physical strategies in onychomycosis topical treatment: a review. *Med Mycol.* 2017;55(5):461-475. **6.** Matsuda Y, Sugiura K, Hasimoto T, et al. Efficacy coefficients determined using nail permeability and antifungal activity in keratin-containing media are useful for predicting clinical efficacies of topical drugs for onychomycosis. *Plos One.* 2016;11(7):1-12. **7.** Sakamoto M, Sugimoto N, Kawabata H, et al. Transungual delivery of efinaconazole: its deposition in the nail of onychomycosis patients and in vitro fungicidal activity in human nails. *J Drugs Dermatol.* 2014;13(11):1388-1392. **8.** Canavan TN, Bevans SL, Cantrell WC, et al. Single-center, prospective, blinded study comparing the efficacy and compatibility of efinaconazole 10% solution in treating onychomycosis with and without concurrent nail polish use. *Skin Appendage Disord.* 2018;5(1):9-12. **9.** Vlahovic TC, Joseph WS. Efinaconazole topical, 10% for the treatment of toenail onychomycosis in patients with diabetes. *J Drugs Dermatol.* 2014;13(10):1186-1190.

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Ortho Dermatologics