Navigating the Prior Authorization process with JUBLIA

JUBLIA is a once-daily treatment for onychomycosis of the toenail.

**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 IMPORTANT SAFETY INFORMATION THROUGHOUT AND FULL PRESCRIBING INFORMATION IN POCKET.**
DIAGNOSIS

- Provide relevant medical records and documentation related to diagnosis of onychomycosis of the toenail
  - Documentation of relevant co-morbid conditions, for example peripheral vascular disease, diabetes mellitus, pain, redness, and swelling surrounding nail tissue.
  - Extent of infection (number of toes affected)

- ICD-10 Code for diagnosis of onychomycosis: B35.1*

- Lab culture/nail biopsy results or KOH test results
  - Confirmation of infection due to *T. rubrum* or *T. mentagrophytes*

LAB DATA

- Failure to submit supporting laboratory data or KOH test results
- Culture or KOH negative for *T. rubrum* or *T. mentagrophytes*

PREVIOUS TREATMENT HISTORY

Documentation of treatment failure with generic oral antifungal therapy (eg, terbinafine/itraconazole) and/or generic topical agents (eg, ciclopirox)

TREATMENT HISTORY

No supporting documentation demonstrating therapeutic failure on generic oral and/or generic topical therapy

IMPORTANT SAFETY INFORMATION (CONT’D)

- 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%).

PLEASE SEE IMPORTANT SAFETY INFORMATION THROUGHOUT AND FULL PRESCRIBING INFORMATION IN POCKET.
**VALUE SAVINGS FOR PATIENTS THROUGH ORTHO DERMATOLOGICS RX ACCESS PROGRAM**

Most eligible commercially insured patients can take advantage of co-pay coupon offers

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Size</th>
<th>Drug Covered Co-Pay</th>
<th>Drug Covered Fills</th>
<th>Drug Not Covered Co-pay</th>
<th>Drug Not Covered Fills(^{\dagger})</th>
<th>Uninsured Amount</th>
<th>Uninsured Fills</th>
</tr>
</thead>
<tbody>
<tr>
<td>JUBLIA®</td>
<td>4 mL</td>
<td>$25</td>
<td>12</td>
<td>$75</td>
<td>2</td>
<td>$125 $200</td>
<td>12</td>
</tr>
<tr>
<td>(efinaconazole) Topical Solution 10%</td>
<td>8 mL</td>
<td></td>
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</table>

*After the indicated number of covered fills, patient will pay uninsured amount for any remaining fills available. If prior authorization is approved, patient will pay the covered amount listed in the table above. Drug not covered is defined as a patient who has commercial insurance but the drug is not covered on the plan’s formulary or has an NDC block, prior authorization, step edit or other restriction that has not been met. Terms and conditions apply. Visit www.orthorxaccess.com or call 1-855-280-0541 for full eligibility criteria, terms and conditions.

\(^{\dagger}\)After the indicated number of fills, patient will pay uninsured amount for any remaining fills available. If prior authorization is approved, patient will pay the covered co-pay price listed.

**IMPORTANT SAFETY INFORMATION (CONT’D)**

- 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 have not been established.

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

**PLEASE SEE ACCOMPANYING FULL PRESCRIBING INFORMATION IN POCKET.**