**INDICATIONS AND USAGE**

JUBLIA® (efinaconazole) topical solution, 10% is an azole antifungal indicated for the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophytes* (1).

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**DOSE AND ADMINISTRATION**

- Apply JUBLIA to affected toenails once daily for 48 weeks using the integrated flow-through brush applicator (2).
- When applying JUBLIA, ensure the toenail, the toenail folds, toenail bed, hyponychium, and the undersurface of the toenail plate, are completely covered. 
  *For topical use only and not for oral, ophthalmic, or intravaginal use.*
  *(2)*

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**FULL PRESCRIBING INFORMATION:**

See the “Instructions for Use” at the end of this Patient Information leaflet for detailed information about the right way to use JUBLIA. 

- Use JUBLIA exactly as your healthcare provider tells you to use it. Apply JUBLIA to your affected toenails 1 time each day for 48 weeks. Adverse reactions reported within 48 weeks of treatment and in at least 1% of subjects treated with JUBLIA and those reported for 48 weeks, using the integrated flow-through brush applicator are:
  - Application site dermatitis 27 (2.2%) 1 (0.2%)
  - Ingrown toenail 28 (2.3%) 3 (0.7%)

**CONTRAINDICATIONS**

- None. *(4)*

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**ADVERSE REACTIONS**

- The most common adverse reactions (incidence >1%) were ingrown toenails, application site dermatitis, application site vesicles, and application site pain. *(6.1)*

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**INFORMATION and FDA-approved patient labeling.**

See the “Instructions for Use” at the end of this Patient Information leaflet for detailed information about the right way to use JUBLIA. 

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**What are the possible side effects of JUBLIA?**

- JUBLIA may cause irritation at the treated site. The most common side effects include:
  - ingrown toenail, redness, itching, swelling, burning or stinging, blisters, and pain. Tell your healthcare provider if you have any side effects that bother you or that do not go away.

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**What should I avoid while using JUBLIA?**

- Do not use JUBLIA in your mouth, eyes, or vagina.

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**Important information: JUBLIA is for use on toenails and surrounding skin only. Do not use JUBLIA in your mouth, eyes, or vagina.**

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**How should I use JUBLIA?**

- See the “Instructions for Use” at the end of this Patient Information leaflet for detailed information about the right way to use JUBLIA.

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**What is JUBLIA?**

- JUBLIA is a prescription medicine used to treat fungal infections of the toenails.

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**Before you use JUBLIA, tell your healthcare provider about all your medical conditions, including if you:**

- are pregnant or plan to become pregnant. It is not known if JUBLIA can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if JUBLIA passes into your breast milk.
- tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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**How would you know if JUBLIA is working?**

- Use JUBLIA exactly as your healthcare provider tells you to use it. Apply JUBLIA to your affected toenails 1 time each day for 48 weeks. Adverse reactions reported within 48 weeks of treatment and in at least 1% of subjects treated with JUBLIA and those reported for 48 weeks, using the integrated flow-through brush applicator are:
  - Application site dermatitis 27 (2.2%) 1 (0.2%)
  - Ingrown toenail 28 (2.3%) 3 (0.7%)

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**How should I store JUBLIA?**

- Store JUBLIA at room temperature, between 68°F to 77°F (20°C to 25°C).
- Do not freeze JUBLIA.
- Store JUBLIA in its tightly closed and store in an upright position.
- JUBLIA is flammable. Keep away from heat and flame. Keep JUBLIA and all medicines out of the reach of children.

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**General information about JUBLIA and Efinaconazole**

- JUBLIA is prescribed for the topical treatment of onychomycosis (infections of toenail) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*.
Step 2:
dry before you apply JUBLIA. Your toenails should be clean and healthy. If you are uncertain about the cleanliness of your nails, you may wish to ask your healthcare provider if you have any questions.

How to apply JUBLIA:

1. Choose the affected toenail (see Figure A).

2. Hold the bottle upside down over the affected toenail and allow the product to moisten the entire brush (see Figure B).

3. Let JUBLIA dry completely (see Figure D).

4. After applying JUBLIA to your toenail, place the cap on the bottle or press/rub the side of the bottle to expel any excess JUBLIA (see Figure C).

5. Wash your hands with soap and water after applying JUBLIA (see Figure E).

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured for:

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by:

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For more information, call 1-888-321-4576.

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Rev. 05/2016  9462902