**JUBLIA** (efinaconazole) topical solution, 10%

9462903 Revs. 09/2016

**FULL PRESCRIBING INFORMATION**

1 **INDICATIONS AND USAGE**

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

2 **DOSAGE AND ADMINISTRATION**

**APPLICATION**

Apply JUBLIA to affected toenails once daily for 48 weeks using the integrated flow-through brush applicator. When applying JUBLIA, ensure the toenail, toenail folds, toenail bed, hyponychium, and the undersurface of the toenail plate, are completely covered.

3 **DOSAGE FORMS AND STRENGTHS**

JUBLIA (efinaconazole) topical solution, 10%

9462903 Revs. 09/2016

For topical use only. (2)

**CONTRAINDICATIONS**

None. (4)

**ADVERSE REACTIONS**

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

To report SUSPECTED ADVERSE REACTIONS, contact Valeant Pharmaceuticals North America LLC at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT INFORMATION and FDA-approved patient labeling.

**REVISED: 09/2016**

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

12.4 Microbiology

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14 CLINICAL STUDIES

14.1 CLINICAL TRIALS

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

**11 DESCRIPTION**

*Sections or subsections omitted from the full prescribing information are not listed.*

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

**What is JUBLIA?**

JUBLIA is a prescription medicine used to treat fungal infections of the toenails. JUBLIA is not known if JUBLIA is safe and effective in children.

**What should I tell my healthcare provider before using 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 milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**How should I use JUBLIA?**

See the “Instructions for Use” at the end of this Patient Information leaflet for detailed information about using JUBLIA. Do not use JUBLIA for a condition for which it is not prescribed for you by your healthcare provider.

**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.

These are not all the possible side effects of JUBLIA.

**Ask your doctor or healthcare provider about side effects. You may report side effects to the FDA at 1-800-FDA-1088.**

**General information about the safe and effective use of JUBLIA**

Before you use JUBLIA, read the instructions for use and patient labeling that is written for health professionals. Do not use JUBLIA for a condition for which it is not prescribed by your healthcare provider. JUBLIA is not known if JUBLIA is safe and effective in children.

**What are the ingredients in JUBLIA?**

Inactive ingredients: alcohol, anhydrous citric acid, butylated hydroxytoluene, C12-15 alkyl cyclomethicone, disopropyl adipate, docosahexaene, and purified water.

**Important information:**

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**Trial 2**

**Vehicle**

**Vehicle**

**JUBLIA**

**Rev. 09/2016 9462903**

Read this Instructions for Use with JUBLIA before you start using it. Talk to your healthcare provider if you have any questions.

**How to apply JUBLIA:**

**Your toenails should be clean and dry before you apply JUBLIA.**

**Step 1:**

Remove the cap from the JUBLIA bottle.

**Step 2:**

Hold the bottle upside down directly over the affected toenail. Turn the bottle upside down, the entire brush will become moistened with the solution. If needed, repeat Step 2 to re-wet the brush.

**Step 3:**

For the big toenail, also apply a second drop to the end of the toenail while applying JUBLIA.

**Step 5:**

Wash your hands with soap and water after applying JUBLIA.

**Step 6:**

Apply JUBLIA once daily to clean dry toenails.

**Step 7:**

Apply JUBLIA to your affected toenails, place the cap on the bottle and screw it tightly.

**Step 8:**

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