

Product Monograph
Including Patient Medication Information

Pr **JUBLIA**®

Efinaconazole Topical Solution

For Topical use

10% w/w of efinaconazole

Topical Antifungal Agent

Bausch Health, Canada Inc.
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Laval, Quebec
H7L 4A8

Date of Authorization:
2026-03-06

Control Number: 301714

Recent Major Label Changes

N/A	N/A
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Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

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Part 1: Healthcare Professional Information

1. Indications

JUBLIA (Efinaconazole Topical Solution, 10% w/w), a triazole antifungal agent, is indicated for:

- the topical treatment of mild to moderate onychomycosis (tinea unguium) of toenails without lunula involvement due to *Trichophyton rubrum* and *Trichophyton mentagrophytes* in immunocompetent adult patients.

1.1. Pediatrics

Pediatrics (< 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

1.2. Geriatrics

Geriatrics (≥ 65 years of age): Of the total number of subjects in clinical studies of JUBLIA, 8.3% were 65 years of age and over while none were 75 years of age and over. No overall differences in safety and effectiveness were observed between these subjects and younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

2. Contraindications

- JUBLIA (Efinaconazole Topical Solution, 10% w/w) is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medical ingredient, or component of the container. For a complete listing, see [6 Dosage Forms, Strengths, Composition, and Packaging](#).

4. Dosage and Administration

4.1. Dosing Considerations

No debridement is necessary when treating onychomycosis with JUBLIA (Efinaconazole Topical Solution, 10% w/w). Removal of previously applied JUBLIA is not required as there is no buildup from daily application. Patients should clip their toenail(s) every four weeks and clippings should be discarded. The unaffected toenail(s) should be clipped before the affected ones.

4.2. Recommended Dose and Dosage Adjustment

JUBLIA (efinaconazole) should be topically applied once daily (preferably at bedtime). Using the brush, JUBLIA should be applied onto the affected toenail(s). A second application should be done onto the affected big toenail(s).

A complete cure may be seen some months after mycological cure is achieved. This is related to time required for outgrowth of healthy nail.

A bottle of 8 mL of JUBLIA contains approximately 380 applications: 1 daily application per each toenail affected. The big toenail requires a second application.

Health Canada has not authorized an indication for pediatric use, see [1.1. Pediatrics](#).

4.4. Administration

JUBLIA (efinaconazole) should be topically applied once daily (preferably at bedtime) to the affected toenails, with the built-in flow-through brush applicator provided. JUBLIA should completely cover the toenail, the nail folds, nail bed, hyponychium and the undersurface of the nailplate.

JUBLIA should be applied to clean dry nails. Once applied, JUBLIA should be allowed to dry thoroughly before touching the treated areas with bed sheets, socks or other clothing (see **Patient Medication Information**).

4.5. Missed Dose

Physicians should use clinical judgement based on the severity of the infection.

5. Overdose

Penetration of JUBLIA (Efinaconazole Topical Solution, 10% w/w) by the topical route leads to low systemic concentration levels. There are no data available on human oral bioavailability however, oral bioavailability in rats (0.4%) is very low.

No reports of overdose were observed in clinical trials either through topical use or by ingestion, however, overdose is unlikely to occur with topical application due to low systemic concentration levels. No specific antidote is known.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition, and Packaging

Table 1 – Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form/ Strength/Composition	Non-Medicinal Ingredients
Topical	Solution, 10% w/w of efinaconazole	Alcohol, Butylated Hydroxytoluene, C12-15 Alkyl Lactate, Citric Acid, Cyclomethicone, Diisopropyl Adipate, Disodium Edetate, and Purified Water.

Description

JUBLIA contains efinaconazole 10% w/w in a clear, low surface tension solution for topical application.

JUBLIA (efinaconazole) Solution 10% w/w is supplied in a white plastic bottle with built-in flow-through brush applicator. Each bottle contains 8 mL of solution.

7. Warnings and Precautions

General

Safety and effectiveness of JUBLIA (Efinaconazole Topical Solution, 10% w/w) have not been studied in patients with a history and/or clinical signs of immunosuppression, with HIV infection, uncontrolled diabetes, pregnant and nursing women, other toenail infection (except *Candida*), toenail infection extended to matrix, patients with only lateral toenail disease, severe plantar (moccasin) tinea pedis.

Concomitant use of other antifungal therapy with JUBLIA has not been evaluated.

Safety and efficacy of daily use of JUBLIA for longer than 48 weeks have not been established.

JUBLIA is flammable; keep away from heat or flame.

Ear/Nose/Throat

JUBLIA (efinaconazole) is **not** for oral use. It is for topical use on toenails and immediately adjacent skin only.

Genitourinary

JUBLIA (efinaconazole) is **not** for intravaginal use. It is for topical use on toenails and immediately adjacent skin only.

Ophthalmologic

JUBLIA (efinaconazole) is **not** for ophthalmic use. It is for topical use on toenails and immediately adjacent skin only.

Skin

If a reaction suggesting sensitivity or severe irritation should occur with the use of JUBLIA, treatment should be discontinued, and appropriate therapy instituted, as recommended by the healthcare professional.

7.1. Special Populations

7.1.1. Pregnancy

There are no adequate and well-controlled studies in pregnant women with JUBLIA. JUBLIA should not be used during pregnancy unless the expected benefit to the mother outweighs any potential risk to the fetus (see [16. Non-Clinical Toxicology](#), [Reproductive and developmental toxicology](#), and [10.3. Pharmacokinetics](#)).

7.1.2. Breastfeeding

It is unknown if JUBLIA is excreted in human milk. After repeated subcutaneous administration, efinaconazole was detected in milk of nursing rats. Because many drugs are excreted in human milk, JUBLIA should not be used in the treatment of nursing women unless the expected benefit outweighs the possibility of any potential risk to the infant.

7.1.3. Pediatrics

Pediatrics (< 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

7.1.4. Geriatrics

Geriatrics (≥ 65 years of age): Of the total number of subjects in clinical studies of JUBLIA, 8.3% were 65 years of age and over while none were 75 years of age and over. No overall differences in safety and effectiveness were observed between these subjects and younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

8. Adverse Reactions

8.1. Adverse Reaction Overview

The data described below reflect exposure to JUBLIA (Efinaconazole Topical Solution, 10% w/w) applied topically to toenails once a day in 1189 patients in two identical Vehicle controlled Phase 3 clinical studies in which 1124 (94.5%) patients were exposed for 24 weeks, and 757 (63.7%) patients were exposed for 48 weeks.

The total number of patients who reported a treatment-emergent adverse reaction (based on adverse events assessed by the Investigator to be at least possibly related to study medication) was 6.1% in the JUBLIA arm and 3.5% in the Vehicle treatment arm.

The most common treatment-emergent adverse reactions reported in patients treated with JUBLIA were application site dermatitis (2.0%) and application site vesicles (1.4%).

The majority of adverse events in the JUBLIA arm were mild to moderate in severity as assessed by the Investigator. Rate of study treatment discontinuation due to adverse events was 2.7% (32/1189) in the JUBLIA group compared to 0.2% (1/401) in the Vehicle group. The most common adverse event that led to study treatment discontinuation was application site dermatitis 1.1% (13/1189).

8.2. Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. Therefore, the frequencies of adverse reactions observed in the clinical trials may not reflect frequencies observed in clinical practice and should not be compared to frequencies reported in clinical trials of another drug.

The treatment-emergent adverse events assessed by the Investigator as definitely, probably, or possibly drug related and reported in ≥ 1% of patients treated with JUBLIA compared with those reported in patients treated with the Vehicle are presented in Table 2.

Table 2 – Drug Related Treatment-Emergent Adverse Events Reported by ≥ 1% of Patients Treated with JUBLIA for up to 48 Weeks

Adverse Event System organ class/preferred term	JUBLIA N = 1189 n (%)	Vehicle N = 401 n (%)
General disorders and administration site conditions		
Application site dermatitis	24 (2.0%)	1 (0.2%)
Application site vesicles	17 (1.4%)	0 (0.0%)

8.3. Less Common Clinical Trial Adverse Reactions

Cardiac Disorders: Ventricular extrasystole (0.1%).

Eye Disorders: Blepharitis (0.1%), eye pruritus (0.1%), and vision blurred (0.1%).

General Disorders and Administration Site Conditions: Application site reactions: discolouration (0.3%), eczema (0.2%), erythema (0.8%), exfoliation (0.6%), irritation (0.3%), pain (0.4%), paraesthesia (0.3%), pruritus (0.4%), and swelling (0.5%).

Infections and Infestations: Nasopharyngitis (0.2%).

Nervous System Disorders: Headache (0.2%).

Skin and Subcutaneous Tissue Disorders: Onychomadesis (0.3%).

9. Drug Interactions

9.4. Drug-Drug Interactions

Topical administration of JUBLIA (Efinaconazole Topical solution, 10% w/w) has very low systemic exposure, therefore potential interactions between JUBLIA and other drugs have not been evaluated (see [10. Clinical Pharmacology](#), [Absorption](#), [Metabolism](#) and [Elimination](#)).

9.5. Drug-Food Interactions

Interactions with food have not been established.

9.6. Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7. Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10. Clinical Pharmacology

10.1. Mechanism of Action

Efinaconazole is a triazole antifungal agent. Efinaconazole inhibits fungal lanosterol 14 α -demethylase involved in ergosterol biosynthesis. The accumulation of 14 α -methyl sterols and subsequent loss of ergosterol in the fungi cell wall may be responsible for the fungistatic and fungicidal activity of efinaconazole. Efinaconazole is shown *in vitro* to be substantially adsorbed to keratin, but keratin binding is weak. Efinaconazole's low keratin affinity is expected to result in increased availability of free drug to the nail infection site.

10.2. Pharmacodynamics

In a guinea pig maximization test, efinaconazole was a mild skin sensitizer. In a Buehler guinea pig test, treatment with a prototype efinaconazole formulation and its vehicle were positive for skin sensitization. However, there was no strong evidence of skin sensitization to JUBLIA in a human repeat insult patch test.

- **Safety Pharmacology**

The safety pharmacology of efinaconazole was characterized after acute exposure in CNS, cardiovascular, respiratory, gastrointestinal and renal preparations and/or animals. Efinaconazole was without effects on core physiological systems or effects were only noted at high doses.

Efinaconazole and the major human plasma metabolite, H3, have negligible or no potential to increase QT interval based on *in vitro* hERG inhibition. This hERG inhibition model used electrophysiological assessment of IKr potassium current in human cells transfected with human hERG cDNA. The H3 metabolite was inactive on hERG-mediated current at 100 mcM (22500 ng/mL) and lower concentrations while efinaconazole produced slight inhibition, 17%, at the maximal soluble concentration of 10 mcM (3480 ng/mL).

Efinaconazole has limited potential for any adverse secondary or off target pharmacological effects because only high parenteral doses produced test article effects. Furthermore, systemic efinaconazole and H3 metabolite exposure in the parenteral animal and *ex vivo* studies are expected to be far above the low ng/mL plasma levels in clinical topical nail therapy.

10.3. Pharmacokinetics

Absorption

Administration of JUBLIA by the topical route leads to low systemic efinaconazole concentrations. Systemic absorption of efinaconazole in 18 patients with severe onychomycosis was determined after application of JUBLIA once daily for 28 days to patients' 10 toenails and adjacent skin. The concentration of efinaconazole in plasma was determined at multiple time points over the course of 24-hour periods on days 1, 14, and 28. Efinaconazole mean plasma C_{max} on Day 28 was 0.67 ng/mL. The mean plasma concentration versus time profile was generally flat over the course of treatment. In onychomycosis patients, the steady state plasma concentration range was 0.1-1.5 ng/mL for efinaconazole and 0.2-7.5 ng/mL for H3 metabolite. In a separate study of healthy volunteers, the plasma half-life of JUBLIA at day 10 following repeat treatment applications repeated to all 10 toenails was 29.9 hours.

Distribution

Efinaconazole *in vitro* binding to human plasma proteins is high, 95.8% - 96.5%. Because of low systemic levels, efinaconazole plasma protein binding is not expected to be clinically relevant. Plasma protein binding was not concentration-dependent over a range 50– 2500 ng/mL. Efinaconazole *in vitro* bound to human serum albumin (95.2%), α 1-acid glycoprotein (85.5%) and to γ -globulin (4.4%). As albumin concentration is high in plasma relative to other proteins, efinaconazole is expected to be mainly bound to human serum albumin *in vivo*.

Efinaconazole penetrates through nails *in vitro* after JUBLIA administration, suggesting drug penetrations to the site of fungal infection in the nail and the nail bed, though clinical relevance is unknown. The penetration of JUBLIA was evaluated in an *in vitro* investigation after daily application of radiolabelled efinaconazole (10%) to human nails for 28 days at 55.1 mcL/cm². After 28 days, the

cumulative radioactivity in the receptor fluid and in the nail plate, on a percent basis of total administered radioactivity, was 0.03% and 0.16% (3.11 mg eq/g), respectively.

The flux rate was relatively constant from Days 18 to 28, mean 1.40 mcg eq/cm²/day, suggesting steady state attainment.

Metabolism

JUBLIA (efinaconazole) is extensively metabolized through oxidative/reductive processes, with the potential of additional metabolite glucuronidation.

Analysis of human plasma confirmed that H3 is the only major efinaconazole metabolite.

JUBLIA is considered a non-inhibitor and non-inducer of the CYP450 enzyme family. In *in vitro* studies using human liver microsomes, efinaconazole inhibited CYP2C8, CYP2C9, CYP2C19 and CYP3A4 enzyme activities at concentrations higher than clinical systemic exposure levels. In addition, *in vitro* studies in human primary hepatocytes showed that efinaconazole did not induce CYP1A2 or CYP3A4 activities. Therefore, efinaconazole is unlikely to affect the pharmacokinetics of substrates of the major CYP450 isoenzymes through inhibition or induction mechanisms (see [10.3. Pharmacokinetics](#)).

Elimination

Efinaconazole metabolites are excreted in urine and bile/feces.

11. Storage, Stability, and Disposal

Store at controlled room temperature (15-30°C). Keep bottle tightly closed and store in an upright position.

12. Special Handling Instructions

Keep out of the reach and sight of children. Solution is flammable; keep away from heat or flame.

Part 2: Scientific Information

13. Pharmaceutical Information

Drug Substance

Non-proprietary name of the drug substance:

Efinaconazole

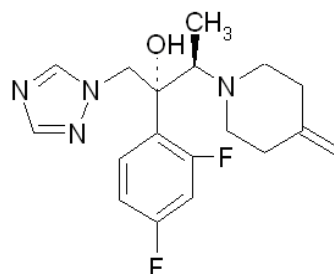
Chemical name:

((2R,3R)-2-(2,4-difluorophenyl)-3-(4-methylenepiperidin-1-yl)-1-(1H-1,2,4-triazol-1-yl) butan-2-ol)

Molecular formula and molecular mass:

C₁₈H₂₂F₂N₄O, 348.39 g/mol

Structural formula:



Physicochemical properties:

White to pale yellow crystals or crystalline powder. Melting point: 86 to 89 °C. The pH of a saturated solution is between 5.5 and 7.5. Practically insoluble or insoluble in water.

14. Clinical Trials

14.1. Clinical Trials by Indication

The safety and efficacy of once daily use of JUBLIA (Efinaconazole Topical Solution, 10% w/w) for the treatment of onychomycosis of the toenail were assessed in two identical Phase III clinical trials which included patients with 20% to 50% clinical involvement of the area of the target great toenail, without dermatophytomas or lunula (matrix) involvement. Patients had positive dermatophyte culture and positive potassium hydroxide (KOH) examination from the target toenail. Patients were not excluded for concomitant *Candida* infection.

Table 3 provides the design and demographics of the 2 pivotal Phase III clinical trials.

Table 3 – Summary of study design and patient demographics for pivotal Phase III clinical trials in onychomycosis

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Age (range)	Sex % M/F
Study DPSI-IDP-108-P3-01	Phase 3, Multicenter, Randomized (3:1), Double-Blind Study evaluating the safety and efficacy of IDP-108 topical solution versus Vehicle in subjects with mild to moderate onychomycosis of the toenails	JUBLIA	618	52.3 (20-71)	74/25
		Vehicle	202	52.0 (18-70)	74/25
		Topical: Once daily			
		Duration of Therapy: 48 weeks			
Study DPSI-IDP-108-P3-02	Phase 3, Multicenter, Randomized (3:1), Double-Blind Study evaluating the safety and efficacy of IDP-108 topical solution versus Vehicle in subjects with mild to moderate onychomycosis of the toenails	JUBLIA	580	50.6 (18-71)	80/20
		Vehicle	201	50.7 (18-70)	81/18
		Topical: Once daily			
		Duration of Therapy: 48 weeks			

Table 4 below displays the primary efficacy results obtained from Study DPSI-IDP-108-P3-01 and Study DPSI-IDP-108-P3-02.

Table 4 – Primary Efficacy Results (Complete Cure) at week 52 in the ITT¹ population

Study #	Primary efficacy endpoint	JUBLIA % (n/N)	Vehicle % (n/N)	p-value ³
DPSI-IDP-108-P3-01	Complete Cure ² at Week 52	18.8% (116/618)	3.5% (7/202)	<0.001
DPSI-IDP-108-P3-02	Complete Cure at Week 52	15.2% (88/580)	5.5% (11/201)	<0.001

¹ITT=Intent to treat.

²Complete Cure at Week 52 (4-weeks after completion of therapy) defined as 0% clinical involvement of the target toenail (toenail is totally clear) in addition to Mycologic Cure, defined as a negative fungal culture and a negative potassium hydroxide (KOH) examination of the target toenail sample.

³p-value from a Cochran-Mantel-Haenszel test, stratified by analysis center.

Study DPSI-IDP-108-P3-01

It was observed that the percentage of subjects who achieved a Complete Cure was greater in the active group than in the Vehicle group by Week 24 and that the percentage of successful subjects in the active group continued to increase over time through the four-week post-treatment follow-up visit (Week 52).

Study DPSI-IDP-108-P3-02

It was observed that the percentage of subjects who achieved a Complete Cure was greater in the active group than in the Vehicle group by Week 36 and that the percentage of successful subjects in the active group continued to increase over time through the four-week post treatment follow-up visit (Week 52).

Table 5 below displays the secondary efficacy results obtained from Study DPSI-IDP-108-P3-01 and Study DPSI-IDP-108-P3-02.

Table 5 – Secondary Efficacy Results at week 52 in the ITT¹ Population

Study #	Secondary efficacy endpoints	JUBLIA % (n/N)	Vehicle % (n/N)	p-value
DPSI-IDP-108-P3-01	Clinical Efficacy ² at Week 52	46% (281/618)	18% (36/202)	<0.001
	Mycologic Cure ³ rate at Week 52	55.3% (342/618)	16.8% (34/202)	<0.001
	Unaffected New Nail ⁴ Growth at Week 52 LS Mean ⁵ (mm)	5.0	1.5	<0.001

Study #	Secondary efficacy endpoints	JUBLIA % (n/N)	Vehicle % (n/N)	p-value
DPSI-IDP-108-P3-02	Clinical Efficacy at Week 52	31% (180/580)	11.9% (24/201)	<0.001
	Mycologic Cure rate at Week 52	53.4% (310/580)	16.9% (34/201)	<0.001
	Unaffected New Nail Growth at Week 52 LS Mean (mm)	3.8	0.9	<0.001

¹ITT=Intent to treat.

²Clinical Efficacy is defined as an affected target toenail area of less than 10%.

³Mycologic Cure is defined as a negative fungal culture and a negative potassium hydroxide (KOH) examination of the target toenail sample.

⁴Unaffected New Nail Growth is defined as the change from baseline in the healthy [unaffected] target toenail measurement for the target toenail.

⁵LS Mean: Least Square Mean.

Table 6 – Mycological Cure¹ Rate at Treatment Period Intervals in the ITT² Population

Treatment Period (week)	Study DPSI-IDP-108-P3-01		Study DPSI-IDP-108-P3-02	
	JUBLIA N=618 n (%)	Vehicle N=202 n (%)	JUBLIA N=580 n (%)	Vehicle N=201 n (%)
12	149 (24)	29 (14)	128 (22)	25 (12)
24	298 (48)	50 (25)	264 (46)	39 (19)
36	339 (55)	41 (20)	301 (52)	38 (19)
48	347 (56)	52 (26)	316 (55)	40 (20)
52	342 (55)	34 (17)	310 (53)	34 (17)

¹Mycologic Cure is defined as a negative fungal culture and a negative potassium hydroxide (KOH) examination of the target toenail sample.

²ITT=Intent to treat.

15. Microbiology

Activity *In Vitro* and *In Vivo*

Efinaconazole has been shown to be active both *in vitro* and in clinical studies for the treatment of toenail infections involving the following microorganisms:

Trichophyton mentagrophytes

Trichophyton rubrum

Efinaconazole is active *in vitro* against strains of the following organisms; however, the safety and effectiveness of efinaconazole in treating clinical infections due to these microorganisms have not been established in clinical trials:

Candida albicans
Trichophyton tonsurans
Trichophyton verrucosum
Trichophyton schoenleinii
Epidermophyton floccosum
Scopulariopsis brevicaulis
Acremonium spp.
Fusarium spp.
Candida parapsilosis
Candida krusei
Candida tropicalis
Microsporum canis

Activity in Animal Models

In a guinea pig model of onychomycosis with *T. rubrum* infection, JUBLIA reduced nail mycological burden by reducing the number of fungi and preventing nail destruction.

Resistance

Efinaconazole drug resistance development was studied *in vitro* against *T. mentagrophytes*, *T. rubrum* and *C. albicans*. Serial passage of fungal cultures in the presence of sub-growth inhibitory concentrations of efinaconazole suggested low resistance development potential. The clinical significance of these *in vitro* results is unknown.

16. Non-Clinical Toxicology

General toxicology

- **Acute Toxicity**

Assessments of efinaconazole acute toxicity were conducted in rat via dermal and subcutaneous (SC) administration, in mice via intraperitoneal administration, and in dog via dermal administration. Efinaconazole was well tolerated in both genders of all 3 species, with all LD₅₀ values higher than 0.5 to 2 grams/kg.

- **Long Term Toxicity**

The long-term toxicity of efinaconazole was evaluated in minipig and mouse via dermal administration and in rats via subcutaneous administration.

Efinaconazole was generally well tolerated in rats with repeated daily doses of up to 30 (males) and 40 (females) mg/kg. The high doses were the maximum tolerated doses, based on increased frequency of severe injection site reactions and a 17% average lower body weight in males compared to controls. No target organs of toxicity were identified at any dose level. Administration of the propylene glycol Vehicle at 2 mL/kg over 6 months was not well tolerated and resulted in mortalities in all groups; Vehicle-related effects included severe dermal clinical signs, and gross and microscopic pathology findings at the injection sites. Early death in several efinaconazole-treated rats was attributed to spinal cord necrosis and urinary tract disease; these lesions also were noted in control rats and were

attributed to the spread of injection site reactions (necrosis, abscessation). The NOAEL was determined to be 10 mg/kg/day in both male and female rats which had an exposure of 70 folds or more for efinaconazole and metabolite H3 as compared to human exposure levels.

In dermal toxicity studies, efinaconazole was well tolerated in minipigs at doses up to 150-200 mg/kg/day. Slight to moderate skin reactions were noted macroscopically and microscopically in all test article groups and Vehicle control and consisted of hyperkeratosis, acanthosis and localized inflammation. These skin effects were attributed to the Vehicle and were not considered adverse due to the mild severity of changes. Microscopic skin changes were resolved by the end of the drug-free recovery period. No target organs were identified at the high dose, which was the maximum feasible dose based on test article solubility and application rate. The NOAEL, established by the 30% strength, was determined to be >150 mg/kg/day which had an exposure of 208 folds for efinaconazole as compared to human exposure levels.

In 13-week dermal toxicity in mice, the systemic exposure to efinaconazole was much higher as compared to minipig. In this study an increase in liver weight and minimal to mild panlobular hepatocellular hypertrophy was observed 30% IDP-108, the local application of IDP-108 and/or the vehicle alone resulted in higher incidences of hyperkeratosis, epidermal hyperplasia, and mononuclear infiltrates in the treated skin. Higher concentration of the test article of 10% and 30% IDP-108 were associated with higher severity of these cutaneous changes compared to controls, and a low incidence of the formation of erosion/ulcers at the treated site. The NOAEL, established by the 30% strength which had an exposure of 700 folds or more for efinaconazole as compared to human exposure levels.

Genotoxicity

Efinaconazole was not mutagenic in a bacterial reverse mutation assay and was not clastogenic in mouse micronucleus and CHL cell chromosomal aberration tests.

Carcinogenicity

In a 2-year dermal carcinogenicity study in mice, efinaconazole showed no evidence of carcinogenicity at doses of up to 140 mg/kg/day (equivalent to approximately 16 and 248 times the clinical maximum use dose based on mg/m² and AUC, respectively).

Reproductive and developmental toxicology

In a fertility and early embryonic development study, subcutaneous efinaconazole administration to rats at doses up to 25 mg/kg/day had no effect on fertility in males or females. Efinaconazole delayed the estrous cycle in females at 25 mg/kg/day but did not have effects at 5 mg/kg/day (equivalent to 58 times the clinical maximal use dose based on AUC).

Efinaconazole was tested for developmental toxicity in pregnant rats and rabbits via subcutaneous administration. At maternally toxic doses, efinaconazole was embryofetal and neonatal lethal in rats but not teratogenic at ≥89 times the AUC at the clinical maximal use dose. The maximal use dose in onychomycosis patients assumes ~42 mg/day efinaconazole (~420 mg/day JUBLIA to all 10 toenails). At lower maternally toxic doses, efinaconazole produced rat placental changes (increased weight and size, and decidua cell vacuolation) and the no observed adverse effect level (NOAEL) was 2 mg/kg/day (equivalent to 10 times the AUC in onychomycosis patients). The rat pre/postnatal NOAEL was 22 times the AUC in onychomycosis patients. In rabbits, efinaconazole was maternally toxic but did not affect embryofetal development at the high dose of 10 mg/kg/day (equivalent to 154 times the AUC in onychomycosis patients).

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **JUBLIA**®

Efinaconazole Topical Solution

This Patient Medication Information is written for the person who will be taking **JUBLIA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **JUBLIA**, talk to a healthcare professional.

What JUBLIA is used for:

- JUBLIA is used to treat an infection on the toenail that does not include the base of the nail caused by certain fungi. It is used in patients who have a healthy immune system.

How JUBLIA works:

JUBLIA stops the fungus from making and maintaining their cell membrane. The membrane becomes weak, the fungus can't survive, and the infection goes away. JUBLIA starts working after the application, but because toenails grow slowly, you may see improvement over time, with clearer, healthier nail growth.

The ingredients in JUBLIA are:

Medicinal ingredient: Efinaconazole

Non-medicinal ingredients: Alcohol, Butylated Hydroxytoluene, C12-15 Alkyl Lactate, Citric Acid, Cyclomethicone, Diisopropyl Adipate, Disodium Edetate, and Purified Water.

JUBLIA comes in the following dosage form(s):

Solution: 10% w/w of efinaconazole.

Do not use JUBLIA if:

- You are allergic to efinaconazole or to any of the ingredients in JUBLIA.
- You are allergic to any part of the container.

JUBLIA is not approved for use in children.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take JUBLIA. Talk about any health conditions or problems you may have, including if you:

- have any other toenail infection.
- have an infection that reach the base of the nail or one that's only on the side of the toenail.
- have severe athlete's foot.
- are taking other antifungal medicines.
- are pregnant or plan to become pregnant. It is not known if JUBLIA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if JUBLIA passes into your breast milk.
- have an HIV infection.
- have diabetes that is not controlled.
- have a suppressed immune system (for example, you can get infections easily).

Other warnings you should know about:

- JUBLIA is not to be used in the eyes.



- Store JUBLIA away from all eye products.
- JUBLIA is not to be used inside the vagina.
- Avoid contact of JUBLIA with your eyes, mouth, nose, lips, or open wounds.
- JUBLIA is for use on toenails and skin right beside the toenail only.
- In case of accidental contact rinse thoroughly with water and consult with your healthcare professional.
- JUBLIA is flammable. You must keep it away from heat and flame.
- Avoid the use of toenail polish, cosmetic toenail products, or having non-healthcare professional provided pedicures while using JUBLIA.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to use JUBLIA:

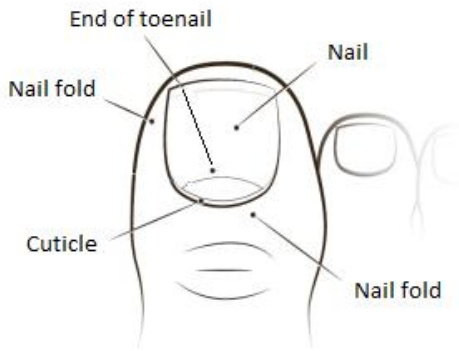
- Use JUBLIA exactly as your healthcare professional tells you to.
- JUBLIA is for use on toenails only.
- Use JUBLIA only on the affected toenail(s) as directed by your healthcare professional.
- It is best to apply JUBLIA at bedtime.
- Apply it with the brush applicator that is built into the bottle. Be sure to completely cover the toenail, around the cuticle, the folds of the skin next to the sides of the toenail, and underneath the end of the toenail.
- To help clear up your infection completely, keep using JUBLIA for the prescribed treatment period as given to you by your healthcare professional. Keep using it for this entire period even if your symptoms begin to clear up. Stopping JUBLIA too soon may cause the infection to restart.
- A QR link to a video is located inside the top flap of the box to show how to apply JUBLIA.

- Apply JUBLIA to toenails that are clean and dry. If you shower, bath or wash your feet before applying JUBLIA, wait at least 10 minutes for your feet and toenails to dry before applying.
- Let JUBLIA dry before covering the treated toenail(s) with bedding, socks or other clothing.
- You do not need to remove dead, damaged or infected areas of your toenail(s) before applying JUBLIA.

Usual dose:

Apply JUBLIA once daily to clean, dry toenail(s) using the built-in brush. If you are treating your big toenail(s) you must apply JUBLIA twice (two coats) to each toenail. All other toes require only one application.

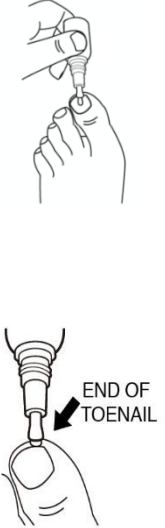

TOENAIL



Clip your toenails every four weeks and always discard the clippings. Be sure to clip uninfected toenails before clipping infected toenails. To avoid spreading the infection, do not share toenail clippers. Be sure to clean the toenail clippers after each use. Daily clipping of the toenails is not needed.

Apply JUBLIA as follows:

<p>Step 1: Remove the cap from the JUBLIA bottle.</p>	A line drawing showing a pair of hands. One hand is holding the JUBLIA bottle, and the other hand is shown removing the cap. An arrow points to the cap being lifted.
<p>Step 2: Before the FIRST APPLICATION on DAY 1: Hold the bottle upside down directly over the affected toenail and gently squeeze the bottle to wet the brush. The entire brush will become moistened with the solution.</p>	A line drawing showing a hand holding the JUBLIA bottle upside down over a toenail. The bottle is tilted so that the brush is positioned directly over the nail.

<p>Step 3: For all applications:</p> <p>a) Hold the bottle upside down and with the moistened brush attached to the bottle, apply JUBLIA by brushing it gently onto the affected toenail(s). The bottle may be gently squeezed to re-wet the brush if needed.</p> <p>b) Gently spread the solution around the cuticle, folds of the skin next to the sides of the toenail, and underneath the end of the toenail.</p>	
<p>Step 4: For the big toenail, repeat the JUBLIA application a second time. Gently brush the solution around the cuticle, nail folds of the skin next to the sides of the toenail, and on the end of the toenail and surrounding skin.</p> <p>Do not squeeze the bottle while spreading the solution.</p> <p>Do not press or rub the brush firmly against the toenail.</p>	
<p>Step 5: After applying JUBLIA, the entire toenail and surrounding skin should briefly glisten with a layer of the solution. Let the treated area dry before covering it with bedding, socks or other clothing.</p>	
<p>Step 6: Replace the cap tightly on the bottle when finished and store upright.</p>	
<p>Step 7: Wash your hands with soap and water after applying JUBLIA.</p>	

Overdose:

If you think you, or a person you are caring for, have taken too much JUBLIA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada’s toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

Try not to miss any doses. If you miss a dose of JUBLIA, apply it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and resume the normal dosing schedule of once a day. Do not double the doses and never make up for the missed dose.

Possible side effects from using JUBLIA:

These are not all the possible side effects you may have when taking JUBLIA. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- skin irritation around the toenail such as redness, itching, burning, or stinging.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Skin reactions: skin irritation around the toenail such as redness, itching, burning, or stinging in the surrounding skin	√		
Uncommon			
Serious skin reactions: skin develops a rash, becomes very red, itchy, swollen, blistered or crusted			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at controlled room temperature (15-30°C).
Store in an upright position.
Keep away from heat or open flame.
Keep the bottle tightly closed when not in use.
Keep out of reach and sight of children.

If you want more information about JUBLIA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website ([Drug Product Database: Access the database](#)); the manufacturer's website www.bauschhealth.ca; or by calling 1-800-361-4261.
- For more information on how to use JUBLIA, please consult www.jublia.ca.

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Date of Authorization: 2026-03-06