CADTH

CADTH COMMON DRUG REVIEW

Patient Input

EFINACONAZOLE (JUBLIA)

(Valeant Canada LP)

Indication: Onychomycosis

CADTH received patient input from:

Canadian Skin Patient Alliance in collaboration with Wounds Canada

August 23, 2018

CADTH

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	**Jublia (efinaconazole) for Onychomycosis**
Name of the Patient Group	**Canadian Skin Patient Alliance in collaboration with Wounds Canada**
Author of the Submission	[redacted]
Name of the Primary Contact for This Submission	[redacted]
Email	[redacted]
Telephone Number	[redacted]

1. About Your Patient Group

The Canadian Skin Patient Alliance (CSPA) is working in collaboration with Wounds Canada for the completion of this submission.

Wounds Canada (Canadian Association of Wound Care), is a non-profit organization dedicated to the advancement of wound prevention and management by being the leading knowledge mobilization organization relating to wounds in Canada (www.woundscanada.ca).

CSPA is registered patient group with CADTH.

2. Information Gathering

CSPA hosted a survey on Survey Monkey in July and August 2018. The survey was advertised on social media platforms of both organizations and shared with personal contacts. In total, we received 9 responses. Of the 9 respondents who provided demographic information: 85% were women; they ranged in age from 26-65; and most were from the province of Ontario. The rest of the responses came from Alberta, Quebec and Saskatchewan.

Additional comments about other treatments used were gathered from on-line disease discussion boards where patients share their experiences with toenail fungus infections and treatments they have tried, including alternatives therapies.

3. Disease Experience

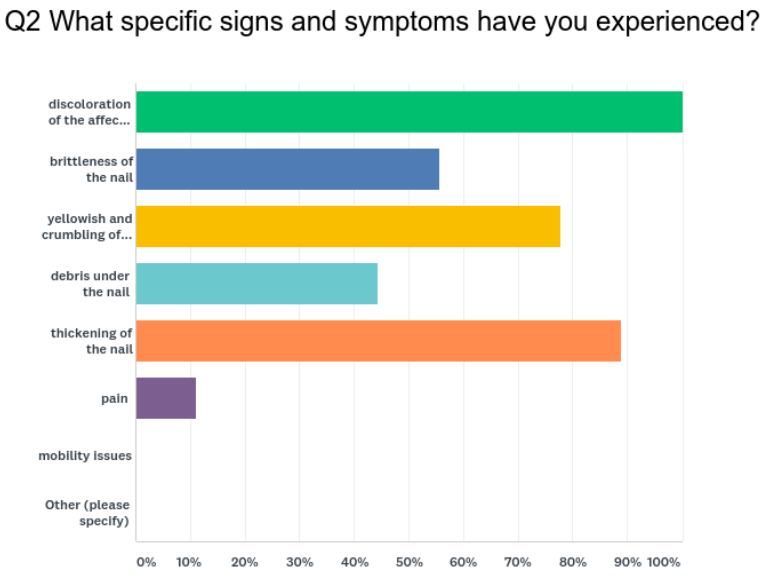
Onychomycosis, commonly known as toenail fungus, is a fungal infection that gets in through cracks in nails or cuts in skin and is estimated to account for up to 50% of all nail problems. Patients experience pain, changes in colour of the nail or a thickening of the nail. Because toes are often warm and damp, fungus grows well there. Left untreated, it can spread to other toenails, skin, or even fingernails.

"I have had toenail fungus for about 15 years. My symptoms include thick, discoloured, brittle nails. I completely avoid wearing any type of sandal...keep nails always covered to hide them."

Infected nails are usually thicker than normal, could be warped or oddly shaped and can break easily. Nails with fungus might look yellow. Sometimes a white dot shows up on the nail and then gets bigger. When fungus builds up under the nail, it can loosen and even separate the nail from the bed. The fungus can also spread to the skin around the nail.

"I have had a toenail fungus in my left great toe for 3 years, at first it didn't bother me but as it got thicker it started to cause pain and pressure which made it difficult for me to wear certain shoes. It was also unsightly and I did not feel comfortable wearing sandals in the summer or to bare my feet at yoga class."

From the survey, this is what we heard from patients:



Proper detection, diagnosis and early treatment is key to prevent long-term damage to the nail. Onychomycosis can be misdiagnosed for other conditions, including nail psoriasis. Patients with diabetes, athlete's foot, or a weak immune system, who smoke, or whose family members have it, are also at a higher risk.

Like many patients living with a visible skin condition, onychomycosis has many psychological and social impacts. Toenail fungus infections can be emotionally distressing and have a negative effect on someone's quality of life. Many patients are self-conscious about the appearance of their nails and report that they stop activities such as yoga or swimming so that others will not see their toenails. From our survey, 66% reported being self-conscious of their appearance and 55% reported embarrassment.

"It has been one year since my nails turned colour and thickened. Embarrassed to walk in sandals in public."

"Had yellow, thick, crumbling nail with thick debris underneath. Did not impact physically. Definitely mentally though. Very self conscious. No open toe footwear or barefoot."

"self conscious and worried about spreading it to family"

4. Experiences With Currently Available Treatments

Common treatments for onychomycosis include topical treatments, oral treatments and physical treatments. Some patients discussed the use of alternative therapies such as Vick's VapoRub, oil of oregano, olive leaf, apple cider vinegar, coconut oil, tea tree oil, grapefruit seed extract. One patient even mentioned soaking her feet in water diluted with listerine and/or bleach. None of these treatments were reported as the "cure" for onychomycosis.

Topical treatments are applied directly to the affected nails such as Penlac which is a nail lacquer. The common side effects of topicals is usually redness and skin irritation around the toenail. Topical treatments such as Jublia can provide an advantage in the treatment of people with diabetes with onychomycosis due to their lack of systemic absorption and drug interactions (5)

Oral treatments are often prescribed for severe fungal nail infections that affect the nail root or matrix, and can be toxic to the liver. Other common side effects include headaches, skin rashes and digestive issues. These drugs are Lamisil and Sporanox.

Physical treatments include laser treatment and removal of the infected nail. Both of these options are expensive and usually need to be used in conjunction with other treatment to actually treat the fungal infection.

From our survey, approximately 1/3 had tried topicals (other than Jublia), 1/3 tried natural health products (or alternative therapies) and 1/3 had tried laser treatment. There was not a question in the survey asking the reason for this therapy choice but it could be depending on whether or not the patient visited a dermatologist or a podiatrist. All of them reported that nothing was effective and that the laser treatment was very expensive.

5. Improved Outcomes

When asked about their views on outcomes that should be considered when evaluating new therapies, our survey respondents indicated that they are looking for the following improvements:

- ✓ Quick results so that "*I am as good as new in the end.*"
- ✓ *"A permanent cure."*
- ✓ *"To have healthy thin, nails."*
- ✓ *"Manage it if not cure it."*
- ✓ *"I expect the discolouration to go away and for my nail to look a normal colour and texture."*

From the on-line discussion board, others stated that they would like less time on treatment (it usually takes 12-18 months to completely heal) and no recurrence of the onychomycosis (which is common.)

6. Experience With Drug Under Review

Eight of the nine respondents to our survey have tried Jublia to treat their toenail fungus infections. The patients who responded to our survey stated that they accessed Jublia through private insurance (25%) or through their health care professional (75%) and paid for the treatment themselves. Only 1 of the 8 reported redness around the nail as a side effect and the others stated that they did not experience any side effects.

In terms of effectiveness, respondents reported some success using Jublia, sometimes in conjunction with other therapies:

"*It actually completely got rid of the fungus, there is no sign of fungus at all."*

"Resolve of the fungal infection in conjunction with laser treatments."

“Nail was clearing.”

The good news is that all 8 respondents with experience with Jublia stated that there no symptoms that Jublia did NOT manage as well as previous treatments they had tried, except for the thickening of the nail.

“It's managed the discolouration so far but the thickening of the nail still kind of persists. Hoping it goes away with time.”

In terms of how easy this drug is in comparison to previous therapies, the six respondents to this question stated that it was easier or the same to use.

All respondents also stated that Jublia should be covered by provincial formularies for the indication of onychomycosis:

“If oral treatments are covered then the topical should be too. Indicated if less than 60% nail involvement so if treated early no need for more harmful oral medications.”

“Yes! Or at least have a special authorization option for people with liver function issues.”

“Why not it is medical problem and as a diabetic could become a bigger problem as I am unable to cut my nails.”

7. Companion Diagnostic Test

N/A

8. Anything Else?

Wounds Canada added the following:

Onychomycosis is a risk factor for ulceration and subsequent amputation in patients with diabetic foot disease (1,2). Diabetic complications, such as peripheral neuropathy is a strong risk factor for onychomycosis which in turn leads to a higher rate of secondary infections. The broken skin allows a portal of entry to bacteria which can lead to infections, such as cellulitis or osteomyelitis that may lead to gangrene and amputation (3,4)

1. Canadian Diabetes Association (CDA). 2013 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Can J Diabetes. 2013;37(S1):S1–S227. Available from: http://guidelines.diabetes.ca/App_Themes/CDACPG/resources/cpg_2013_full_en.pdf.
2. International Diabetes Federation (IDF). Clinical Practice Recommendations on the Diabetic Foot 2017. 2017. Available from: www.idf.org/e-library/guidelines/119-idf-clinical-practice-recommendations-on-diabetic-foot-2017.html.
3. Gupta AK, Humke S. The prevalence and management of onychomycosis in diabetic patients. Eur J Dermatol. 2000;10(5):379–84.

Botros M, Kuhnke J, Embil J, Goettl K, Morin C, Parson L, et al. Best practice recommendations for the prevention and management of diabetic foot ulcers. In: Foundations of Best Practice for Skin and Wound Management. A supplement of Wound Care Canada; 2017. 68 p. Available from: www.woundscanada.ca/docman/public/health-care-professional/bpr-workshop/895-wc-bpr-prevention-and-management-of-diabetic-foot-ulcers-1573r1e-final/file

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

   No.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

   No.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
Valeant	X			

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Kathryn Andrews-Clay
Position: Executive Director
Patient Group: Canadian Skin Patient Alliance
Date: August 23, 2018

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No relevant organizations have provided financial payment.				

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Sheri Pilon
Position: Senior Marketing Manager
Patient Group: Wounds Canada
Date: August 23, 2018