

CADTH COMMON DRUG REVIEW

Patient Input

OZENOXACIN (OZANEX)

(Ferrer Internacional, S.A)

Indication: Impetigo

CADTH received patient input for this review from:

Canadian Skin Patient Alliance

February 9, 2018

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1. About Your Patient Group

The Canadian Skin Patient Alliance is a registered patient group with CADTH.

The Canadian Skin Patient Alliance (CSPA) is a non-profit organization that serves patients with dermatological conditions, diseases and traumas in Canada. It focuses on education and advocacy for these patients and for its 20+ affiliated disease-specific organizations in Canada. The CSPA has a steady social media community as well as thousands of readers via our award-winning magazine Canadian Skin (À propeau in French).

2. Information Gathering

We developed a patient survey (hosted on Survey Monkey) that was used to collect information and feedback about the patient and caregiver experience with impetigo. The survey was advertised on our social media platforms several times, as well as shared with mom bloggers, Affiliate Member groups, and personal contacts. We also researched on-line disease discussion boards where patients share their experiences with impetigo as well as treatments.

Unfortunately we had little uptake to our survey: 5 respondents with no one who had experience with the treatment. This was not surprising as there were no Canadian Clinical trials for Ozanex.

3. Disease Experience

Impetigo is a bacterial skin infection that causes red sores to form. These sores can break open, ooze fluid and develop a yellowish crust over them. These sores can occur anywhere on the body. Impetigo is a very common infection and while it can occur in both adults and children, it is seen far more often in children. Impetigo is very contagious and can spread through contact. Impetigo can be very itchy and can also be spread to other parts of the body through itching.

Most of those surveyed experienced impetigo on their hands and feet or nose and mouth, and approximately 20% reporting it on their buttocks or entire body.

In adults, impetigo may occur along with other skin problems, including eczema, or after an upper respiratory tract infection.

All of those surveyed experienced red sores that crusted over and 60% said the sores increased in size and number while 40% indicating the sores turned into large blisters. About 60% indicated that the itching was a problem, and said that they "Itched so bad that it starts bleeding" and 40% complained of soreness/pain.

Patients also mentioned fever as a symptom that caused the most difficulty and that "it was awful and took everything out of me". One patient indicated that they "couldn't function in normal every day activities" and that they experienced "extreme pain and couldn't sit for weeks" due to the impetigo on their buttocks.

Several mentioned the stigma of having such a "horrible" condition and that they were self-conscious of their outward appearance. They felt isolated knowing that the condition is so contagious.

One patient indicated that they also had experienced cellulitis as a complication of having impetigo.

Since impetigo is most prevalent in children who cannot care for themselves, the biggest impact on the families of the patient is that they are tasked with the care of the patient. Given how contagious it is, children are unable to attend

school or daycare for days to weeks, depending on the severity. Parents are impacted by having to stay home from work to care for their children, some indicating they "missed 30 days of school. "I had to take days off work and my daughter missed school and playroom" The other consequence of it being so contagious is that the patients can easily pass it on to their caregivers. "It is so contagious it spread quickly through our whole family". Like many childhood illnesses, there can also be outbreaks in schools and daycares which complicates the situation for all who have been in contact.

Another impact on the family is the time to clean sheets, towels and toys. This is important, but time consuming task that is imperative to limit the spread of the disease.

4. Experiences with Currently Available Treatments

Current treatments for impetigo are both topical and oral antibiotics including, Bactroban, Cephalexin and Amoxicillin. It was clear from our survey that patients respond very differently to each treatment and what worked effectively for one did not work at all for another. Some would try one medication, and see clearance of the infection, only to have it come back.

Patients indicated that current treatments were messy and sticky. It was difficult to apply the current treatments on young children, particularly babies and have them keep the medication on their skin. "It was difficult to keep it on their face without having them rub it off."

The side effects from the current treatments that patients reported included yeast infections, bad breath, diarrhea, nausea, or that the medication just stopped working altogether.

One patient even indicated that it was costly due to not having health insurance at the time and that "the pills and creams were very expensive so the doctor ended up giving us samples to try because they would all seem to stop working."

Patient also indicated the time it took for the treatments to be effective was a problem resulting in missed days from work and school and the treatment "would work and then stop working and it would come back again just when it looked like it was getting better".

5. Improved Outcomes

Having a medication that is shown to be effective quickly will limit the potential spread of the infection to others, as well as ease the pain symptoms that have been reported more quickly. Having a treatment that is quick and effective will mean less missed days at school/work

The pain control is another issue for impetigo patients. Patients indicated that the pain "took everything out of me" and that it could take a long time for the pain to subside. Those surveyed indicated that limiting the potential to spread the infection, as well as preventing "the pain that spreads like wildfire" would be something they consider important in a new treatment.

One patient stated "just give me a pill and/or cream that work".

6. Experience with Drug Under Review

We did not have any survey respondents who had specific experience with Ozanex. This was not surprising as there were no Canadian clinical trials for Ozanex.

7. Anything Else?

Given that impetigo is highly contagious, and that current medications may not work consistently from one patient to the next, it is important to have treatment options available to patients, in particular ones that are effective for the symptoms of impetigo including persistent infections, itch and pain.

The number of respondents to this questionnaire who have experience with Ozanex is not reflective of the need for this new treatment but of the current limitations in reaching patients who were involved in the clinical trials. There were no Canadian clinical trial sites for this treatment.

Also, given that it is often young children who suffer from impetigo, having a treatment available that is easy to use and can be effective in a short period of time would be most welcome. Thank you for considering the patient experiences in this questionnaire.

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 we did not receive outside help.

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 we did not receive outside help.

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
Cipher Pharmaceuticals			X	
GSK		X		
Pfizer			X	
CIHR-IMHA		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.

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 Position: Executive Director
 Patient Group: Canadian Skin Patient Alliance
 Date: February 7th, 2018