

## Welcome to BC PharmaCare's Public Input Questionnaire for drugs being reviewed under the B.C. Drug Review Process.

This questionnaire is for **[rifaximin (Zaxine)]**.

**Patient Groups have to register before completing the questionnaire.** Not sure your group is registered? Check our list of [registered groups](#).

Your group can complete this patient group questionnaire only once. If you submit multiple questionnaires, only your last submission will be sent to the Drug Benefit Council for consideration.

**To protect the privacy of members in your group, please do not include in your response names of individuals or companies, locations, or any other information that might identify them or anyone else.**

### Completing the questionnaire

**Mandatory questions are flagged with a red asterisk (\*).**

*If you decide not to provide the required information, click the CANCEL button at the bottom of this page to exit the questionnaire. To protect your privacy, your browser window will close.*

You do not need to answer all the optional questions. You need only answer those that you think apply to patients in your group.

To protect your privacy, please close this browser window after you complete this questionnaire.

### Respondent information

**To have your input accepted, you must complete the Confirmation of Eligibility, Contact Information and Conflict of Interest Declaration sections of this questionnaire.**

### Confirmation of eligibility

1. I am a resident of British Columbia, **AND**

I am an authorized member of a Patient Group that represents B.C. patients who have the condition or disease for which this drug is used.\*

X

Yes

No

## Contact Information

**Your organization's contact information will only be used to retrieve your submission if you submit a request under the Freedom of Information and Protection of Privacy Act (FOIPPA). It will not be used for any other purpose.**

Your organization's name, however, will be included as part of your submission to the Drug Benefit Council.

2. **Patient Group Name and name of representative completing this questionnaire\***  
HepCBC Hepatitis C Education and Prevention Society, representative completing questionnaire: REDACTED

3. **Organization's Address \***  
#20 – 1139 Yates Street, Victoria, BC

4. **Postal Code \***  
V8V 3N2

## Conflict of Interest Declaration

To make sure the Drug Review process is objective and credible, everyone who provides input has to tell us about any possible conflict of interest.

A conflict of interest exists if you, an immediate family member or your organization might benefit from the outcome of the review. For example, if you or your family own stock in the company that makes the drug, there could be a financial benefit IF PharmaCare decides to cover the drug. If your organization receives funding from the drug company, there could be a financial benefit (such as ongoing or increased funding) IF PharmaCare decides to cover the drug.

Examples of conflicts of interest include, but are not limited to, financial support from the pharmaceutical industry (e.g., educational or research grants, honoraria, gifts and

salary) as well as affiliations or commercial relationships with drug manufacturers or other interest groups.

Even if you or an immediate family member, or your organization, has a conflict of

interest, your input will still be considered as long as you declare the conflict of interest in your answers to the questions. All information you provide is protected under the Freedom of Information and Protection of Privacy Act.

5. Do you have any Conflict(s) of Interest to declare?  
(If you answer "yes," please complete Question 6 below.)\*

X

Yes

No

6. Describe any Conflict(s) of Interest below.  
(Complete this question only if you answered "yes" to the previous question)

HepCBC Hepatitis C Education & Prevention Society has received funding for hepatitis C-oriented projects such as publishing educational materials, organizing educational forums, attending and presenting at educational conferences, advertising in newspapers (events and hepatitis C patient awareness), and holding awareness activities from the following pharmaceutical companies over the last four years: Merck Pharmaceuticals, Hoffman-LaRoche, Vertex Pharmaceuticals, Gilead Sciences, Janssen Pharmaceuticals, Bristol Myers Squibb, Boehringer-Ingelheim, and AbbVie. In addition, the author of this report has attended several educational conferences and meetings for which registration and travel expenses were funded by the pharmaceutical companies listed above.

## Questions on drug under review

Question 7 is mandatory; all other questions in this section are optional.

7. Have you read the PharmaCare information sheet for this drug?\*

If you would like to read this information now, click on the "this drug's information sheet" link in the *What this drug is for* column of the [List of Drugs Under Review](#). The information sheet will open in a new window.

\*

X Yes, I have read the information sheet

No, I have not read the information sheet

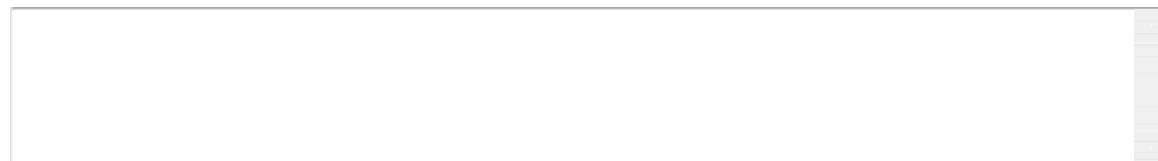
8. Describe how the condition or disease for which this drug is used affects the day-to-day life of patients in your group.

As a patient group for those affected by hepatitis C, we at HepCBC have had much experience with people suffering from both minor and major forms of hepatitis

encephalopathy (HE). It is indeed a very debilitating condition, even when it manifests in its less severe form, and can be episodic. In the very end stages of liver disease, it is a nightmare for both patients and families. Some of us have watched HCV+ people and their families suffer for years, on and off, as HE results in loss of confidence, a job, relationships, and ensuing financial hardship, further agitation, alienation, isolation, anger, and depression. We have also seen people in their last couple weeks of life, first in a state of total agitation and confused, irrational anger at their caregivers, later slipping into a coma. As patients with liver disease, we greatly fear this state, particularly any hurtful things we might say to dear friends, family, and caregivers, especially as this would be their final memory of us. Patient voices:

“I have Primary Biliary Cirrhosis and Sjogren’s Syndrome. My more severe symptoms include shaking of hands or arms, agitation, excitement, disorientation. drowsiness and confusion, slowed or sluggish movement, and problems concentrating. In short I have problems functioning well in my day-to-day life. Every activity in my life is affected. Fatigue prevents many activities...Although I am the one with the disease, my husband was extremely effected also. I needed careful watching, I was never left alone for any extended time, and all my actions were monitored. Since a lot of my bizarre behaviour occurred at night, he always slept lightly so that he could hear me if I was out of bed.”

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“I had a liver transplant in April 2002. I was psychotic by this time. I had 7 hemorrhagic bleeds over several years. MRI’s demonstrated encephalopathy. For a long time before the transplant large portions of memory were missing. I was argumentative and belligerent. I had 2 car wrecks and don’t remember those. I would get lost going home. And couldn’t stay in my lane on the freeway... I have peripheral neuropathy and can not to this day hold my balance if I try to walk heel to toe. I have permanent brain damage affecting memory and sleep...Rarely over the last decade have I been able to sleep 4 hours. I had an Extensive Neuropsychiatric Evaluation after the transplant and the diagnosis was cognitive impairment due to slow processing speed...If my mind is a little cloudy I do not drive “



If the patients in your group have tried the drug under review, please tell us about the effects they experienced.

A few patients who responded to our request for input have been taking Zaxine for an extended period (actually not Zaxine but Xifaxan, rifaximin's US tradename) through Salix Pharmaceutical's "Special Access Program" for Canadian patients. This program, in which Canadian hepatic encephalopathy patients received this drug free of charge, ran between 2010 and 2013. It stopped on Nov. 7, 2013 as Canadian law requires such a program to be terminated within 90 days of Health Canada's NOC (Aug. 13, 2013). Presently it is only available through direct purchase. This is a terrible burden for patients such as these who really need this critical drug benefit covered.

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“When I was released from the hospital, I went to see my hepatologist. As it happened, he was able to get access to RIFAXIMIN through a special access program. [SAP through US manufacturer, Salix]. This drug gave me a new life! I could actually feel the foginess dissipate. I can focus, multi-task and problem solve, all the cognitive abilities one expects to have. My coordination has returned. I still have some trouble remembering events and physically I have very limited stamina but I have come

such a long way all as a result of RIFAXIMIN.””

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(Patient with PBC and Sjorgren’s Syndrome): “For several years, I have taken both ZAXINE (through Compassionate Study program of Salix) and LACTULOSE. LACTULOSE causes loose stools and for that reason I use it seldom.”

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(Partner of patient with PBC and Sjorgren’s Syndrome): “Since patient began taking ZAXINE the impact of her condition on my life has been considerably less. Less worry because patient is more energetic, mood is more optimistic. Concentration and focus is better. Fatigue improved. Able to eat foods containing protein again. Able to gain some weight, now back to normal. Looks good too. Definitely less fatigue. Better daily function. ZAXINE works beyond our expectations to help clear up HE symptoms.”

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(Patient with PBC and Sjorgren’s Syndrome): “Good. Can function better. Improved Feeling of well being. I have been on the study for ZAXINE and I have been on the drug for a few years. Made my Life livable. Have been using ZAXINE for a few years. Improves my wellbeing and health. No side effects! I can live again.”

“Positive effects on my symptoms (shaking of hands or arms, agitation, excitement, disorientation, drowsiness or confusion, slowed or sluggish movement, and problems concentrating. The best result is it allows me better concentration. I am able to focus better with less Confusion and improvement in Calmness.”

“There are no adverse events or Negative Effects. And it sure is easier to use than the other drugs. More convenient. Less unpleasant.”

“Now with taking ZAXINE, I can live a good life with dignity.”

“When the Study concluded; there was no access to ZAXINE in Canada. I contacted [representatives’ names] from Salix, USA. They have been wonderful and have been providing me with ZAXINE on a compassionate level. I am grateful to [representatives’ names] from Salix USA for allowing me to have a better quality of life!”

“Unfortunately ZAXINE is Out of Reach expensive, \$1400 to \$1600 a month so (without reimbursement by Pharmacare) is not accessible as of yet to the public.”

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9. What drugs or other treatments have the patients in your group used, or are currently using, for

the condition or disease for which this drug is used?

Lactulose, Ursodiol, Ciprofoxacin

*Please list all of the drugs and tell us about the experience of the patients in your group with each treatment.*

(liver transplant HE sufferer): "All I had was LACTULOSE which I absolutely hated the sweet syrupy taste. I had to stay near a toilet-because it would act 0-4 hours after taking. I eventually had to take it because I could not hold my balance or walk straight."

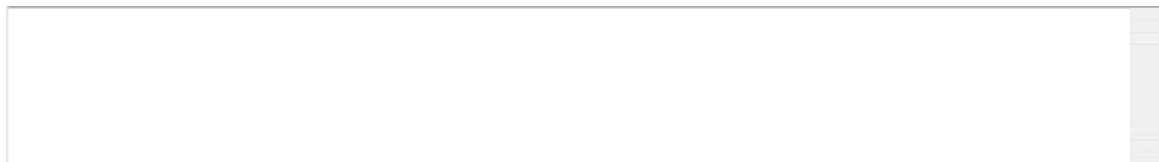
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(Primary Biliary Cirrhosis [PBC] HE sufferer): "In 2007 I was diagnosed with Primary Biliary Cirrhosis. My hepatologist prescribed URSODIOL. At that time I was virtually symptom free and remained that way until 2011 when my first attack of HE occurred. It was characterized by disorientation, loss of coordination, slurred speech, stumbling gait, and inability to focus mentally. Because of this [NOTE: unusual for PBC] presentation, it was felt by my doctor that I had had a slight stroke. However, in consultation with the stroke clinic it became clear that that was not the case. The symptoms lessened but never really disappeared, but nobody really knew what to do with me. I went to Emergency three or four times but there was never a conclusive diagnosis. One doctor prescribed LACTULOSE but, since I didn't really understand its purpose I was inconsistent about taking it. I continued in this foggy state for over a year. The attacks occurred several times. I was prescribed CIPROFLOXACIN; it was somewhat helpful for a short time but soon had no effect in the long term. Fifteen months after my first HE attack, I had an extremely serious attack. Not only did I demonstrate the earlier mentioned symptoms but in addition I was delirious and behaving in a totally uncontrolled manner. To this day, I have absolutely no recollection of those two days."

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(HCV+ patient who works as a volunteer at HepCBC): "I have known six patients with severe HE, and all lost their jobs and became alienated from their families during their periods of HE. Two eventually got liver transplants and are doing great now. One is still awaiting a transplant and though he is out of a hepatic coma at present, he is dealing with HE and related depression daily. Two almost died and are still quite ill, but have overcome most of their HE, enough to do volunteer work but not to hold down a paying job. The last died a terrible death over a very short time. All of these six patients took LACTULOSE alone for their HE and other symptoms of ESLD; no other drugs were used."

"LACTULOSE helped keep the first three alive while awaiting a liver, though they were slipping in and out of coma. The two who now volunteer are still taking LACTULOSE regularly, and it helps them maintain their mental strength. The patient who died did not respond at all to LACTULOSE, and died of an intestinal obstruction. If she had been able to take ZAXINE, she might be alive today."



10. Please tell us why your organization believes this drug should be included in the BC PharmaCare program.

HepCBC fully supports listing ZAXINE in Canada for use with any patient with HE, either added to other drugs such as LACTULOSE, or as a stand-alone, depending on the patient's needs. We recognize the cost factor would likely not make it the first drug to try, but to have it available (and financially accessible) to deal with this terrible condition would be a real blessing to these

patients and their loved ones. Perhaps if ZAXINE were available to them, they would be able to hold down a paying job and support their families. Doctors could at least try ZAXINE with patients such as those if it were covered by Pharmacare.



## Conclusion

Thank you for your organization's input to B.C. PharmaCare's review of this drug.

Once the survey period for this drug ends, we will send everyone's responses to the Drug Benefit Council for consideration when they make their drug coverage recommendations.

Before your input is forwarded to the Drug Benefit Council, we will remove all personal information, including the name(s) of patients and any other identifying details. The name of your organization, however, will be included as part of your submission.

Would you like to learn more about the drug review process? Visit the [drug review process overview](#) on the PharmaCare website.

Would you like to learn about the drug review decisions? Visit the [PharmaCare drug coverage decision summaries](#) on the PharmaCare website.

*Click the DONE button to submit your input and close this questionnaire.*

**After you have clicked "DONE," your browser may ask you whether you want to close the questionnaire window. To protect your privacy, please answer "yes" at the "close this window?" prompt.**