

WHAT IS PREZCOBIX®?

- PREZCOBIX® is a prescription HIV-1 (Human Immunodeficiency Virus 1) medicine used with other antiretroviral medicines to treat HIV-1 infection in adults. HIV is the virus that causes

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Diarrhea Troublesome Side Effect Among HIV+; Mytesi Could Help

by Winnie McCroy
EDGE Editor
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There is clear evidence that diarrhea among HIV-positive patients is under-recognized and underreported. A new [study](#) by Patrick Clay, Pharm.D, reveals that HIV patients experience and self-medicate GI-symptoms, such as diarrhea, without their doctor's knowledge -- the study used 'real world' data comparing healthcare providers' perceptions and clinical records to their patients' perceptions of ART tolerability and self-management.

Napo Pharmaceuticals CEO and Founder Lisa Conte noted that according to a recent [study](#), one in five people living with HIV experiences diarrhea. Patients often try to manage their diarrhea with lifestyle restrictions such as limiting food intake,

avoiding travel or altering work schedules to minimize the risk of accidents. They may also use products that can cause constipation or which have not been proven safe and effective in people with HIV.

This is a classic case of "Hear No Evil, See No Evil, Speak No Evil;" patients don't report the true extent of their diarrhea, and physicians don't ask about the impact of diarrhea on their patients' quality of life.

"Diarrhea can be embarrassing, and it is not a topic that people usually bring up on their own," said Conte. "Also, people living with HIV typically don't report diarrhea to their physician because they have been dealing with it for a long time and they don't know their physician has anything new to offer them. They often have resorted to adjusting their lives, limiting activity and social interaction. Physicians typically only ask patients if there has been a change in their bowel habits, rather than asking about the impact of diarrhea on their daily lives. This disconnect results in the underreporting of diarrhea in people living with HIV."

Her colleague, the HIV specialist Rodger D. MacArthur, MD, Professor of Medicine, Division of Infectious Diseases at the Medical College of Georgia, said doctors should always ask patients living with HIV about their diarrhea "at least once every 6 months, including details like frequency, amount, consistency and associated symptoms such as cramping, etc. And for patients who may have been 'suffering in silence' for a long time, doctors should change their question from 'have there been any changes in your bowel habits' to 'are there any issues you are having with diarrhea or loose stools that you want to discuss?'"



Bizjournals.com (Source:Dr. Lisa Conte)

The study noted that 66 percent of healthcare providers interviewed revealed that diarrhea is the most troublesome adverse effect of antiretroviral therapy (ART). At the same time, the study revealed that physicians reported only 19 percent of their HIV-positive patients experience diarrhea and 7 percent were treated with antidiarrheals vs. patient reports that indicated only 21 percent experience diarrhea and 10 percent were treating with antidiarrheals.

"Challenges included lack of time, focus on adherence to ART, focus on overall health and well-being, and focus on recent lab results," MacArthur explained. "But one of the greatest challenges is that there are many things that receive more focus in a normal office visit such as recent lab results and adherence to ART, so sometimes diarrhea is not discussed. Also, patients may be self-treating with over the counter anti-diarrheals and may not ask their doctor about treatments

because they may not be aware that a specific prescription treatment is available."

Faced with such large numbers, it is imperative that physicians and HIV-positive patients are made aware that a specific treatment is available to treat diarrhea.

"Interestingly, nurses who see people living with HIV tell us that the one common question doctors consistently ask patients is 'Has there been any change in your bowel habits?' The problem is that for many people living with HIV who have suffered from diarrhea for a long time, there have not been any changes in their bowel habits because it is an ongoing and recurring issue," said Conte. "Therefore, doctors instead need to ask, 'Are there any issues you are having with diarrhea or loose stools that you want to discuss?'"



Mytesi Could Help

This fall, Napo Pharmaceuticals announced the launch and general availability of Mytesi (crofelemer), the only anti-diarrheal studied in and FDA-approved for the relief of diarrhea in HIV-positive patients. As part of the launch of Mytesi, which was previously marketed as Fulyzaq, Napo announced the availability of two important patient assistant programs.

"This is the first and only antidiarrheal drug that was specifically studied in and FDA-approved for people living with HIV," Conte explained. "Mytesi provides relief of symptomatic diarrhea in people living with HIV and works in a unique way that does not cause constipation. Also, there are no drug interactions, and Mytesi can be taken with any antiretroviral therapy."

Conte said that as part of the launch, they have initiated an aggressive advocacy program to increase awareness of Mytesi among people living with HIV/AIDS, their healthcare providers and AIDS service organizations.

"We want to educate patients and their healthcare providers to let them know this product is available and hope to spark a conversation among those that are suffering from diarrhea," she said.

MacArthur, who was an investigator and author of the ADVENT study of crofelemer (Mytesi), pointed out that it has a well-understood and specific mechanism of action, and has been studied in people living with HIV. Conversely, the anti-motility drugs (e.g. Imodium and Lomotil) have a non-specific mechanism of action which means they basically shut down gut movement.

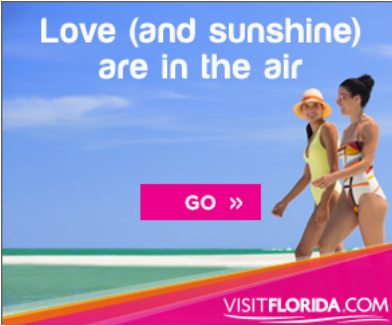
As such, they are associated with many side-effects, from the "somewhat annoying" post-diarrhea constipation, to the very serious increased risk of very serious complications if the diarrhea was caused by pathogens such as *Clostridium difficile* (C. diff). The use of anti-motility agents in the presence of ongoing infection such as C. diff. is contraindicated and quite dangerous. In addition, these drugs have never been studied for safety in people living with HIV.

In short, "Mytesi fills an unmet need for the treatment of non-infectious diarrhea in this population," said MacArthur.

For more information, visit mytesi.com

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Winnie McCroy is the Women on the EDGE Editor, HIV/Health Editor, and Assistant Entertainment Editor for EDGE Media Network, handling all women's news, HIV health stories and theater reviews throughout the U.S. She has contributed to other publications, including The Village Voice, Gay City News, Chelsea Now and The Advocate, and lives in Brooklyn, New York.

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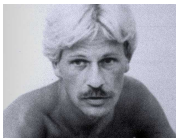
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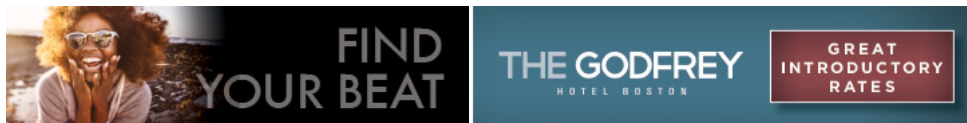
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