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Perez, Thomas

From: JoanneSoucy
Sent: Friday, April 05, 2002 7:47 PM
To: pereztc@cder.fda.gov
Subject: Lotronex, Please

Dear Mr. Perez:

I am a 45 year old female who has been suffering from IBS since 1979.

It's hard to describe the kind of life I had before lotronex. It was a very limited social life. I was unable to sit through a movie, or go shopping at the mall, or go out to eat without the URGENT need to use the restroom, and not just one time, but numerous times, always with pain and diarrhea. I'm also underweight as nothing stayed put long enough for my body to absorb. My career options were limited, as even going on an interview was a stressful, traumatic event, as I always worried about whether or not I would have an attack.

I became a homebody, declining many invitations from family and friends because of this painful, embarrassing condition. I would manage to get through a day of work, then come home and crash. The worst part was not being able to do many things with my sons while they were growing up. I could never go anywhere with them by myself, whether it be a school function, doctor's appt., etc. I would always need to take another adult as inevitably I would need to run to a bathroom numerous times, some times not making it in time.

Well, they're grown now, so, unfortunately, there's no going back to recapture those days. If only I had Lotronex back then. My life would have been completely different.

Since being on Lotronex, I've gone to many movies and sat through the whole thing. I'm able to enjoy shopping at the mall and have eaten out at restaurants. I've even been able to volunteer my time to help my community. These things may not seem big to someone who doesn't have IBS, but they are enormous to me. Normal people take the simple things for granted.

I've been on Lotronex since March of 2000. I'm one of the lucky people who still have Lotronex, but, unfortunately, will be consuming the last of my supply within the next 10 days. After that, I will resort to an off-label prescription called Elavil (amitriptyline) to see if this will help my IBS. I'm trying to think positive, but have heard mixed results from many people who have tried it.

I've resigned from my volunteer position as I will no longer be able to participate in their activities. Movies will be out of the question, and eating out will be a thing of the past. I'll most likely have to shop by mail-order catalog instead of enjoying a day at the mall with friends.

Remember, I've been on Lotronex for over two years now. I had a colonoscopy in June of 2001, while on Lotronex, with no negative results. No signs of ischemic colitis or anything else. I take 1/2 mg daily. Although 2 mg. daily may be what's needed for some, 1/2 mg daily was sufficient for me. I started at 2mg and knew immediately it was too high a dosage. I discussed the reduced dosage with my physician, and we agreed less is always better.

I would respectfully request that you and your group approve the return of Lotronex. Prior to taking the medication, I researched the drug, discussed the side effects with my physician and understood the risk I was taking. I was, and still am, willing to take that risk. Let it be the decision of the patient to determine whether the benefit vs. risk ratio is enough for them to take Lotronex.

Regards,
Joanne Soucy

4/9/02