



Common Drug Review *Patient Group Input Submissions*

Mirabegron (Myrbetriq) for Overactive Bladder

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.

The Canadian Continence Foundation — permission granted to post.

CADTH received patient group input for this review on or before June 13, 2014

CADTH posts all patient input submissions to the Common Drug Review received on or after February 1, 2014 for which permission has been given by the submitter. This includes patient input received from individual patients and caregivers as part of that pilot project.

The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations. While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

The Canadian Continence Foundation

1. General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Mirabegron (Myrbetriq)for Overactive Bladder
Name of the patient group	The Canadian Continence Foundation
Patient group's contact information:	P.O. Box 417 Peterborough, Ontario K9J 6Z3 (705) 931-4488 www.canadiancontinence.ca
Permission is granted to post this submission	Yes

1.1 Submitting Organization

Founded in 1986, The Canadian Continence Foundation (formerly The Simon Foundation for Continence Canada) is the only national non-profit organization serving the interests of people experiencing incontinence. The organization is lead by people with incontinence and by professionals from all health disciplines. The Canadian Continence Foundation (TCCF) is supported by donations from the public, healthcare professionals and private industry.

The mission of TCCF is to enhance the quality of life for people experiencing incontinence by helping them and/or their caregivers to confidently seek and access cures and treatment options. To this end, TCCF will implement and encourage important public and professional education, support, advocacy and research to advance incontinence treatment and/or management.

The Canadian Continence Foundation offers a wealth of information on incontinence. Books, videotapes, and newsletters are available. We operate a toll free number at 1-800- 265- 9575. Each year the Canadian Continence Foundation responds to thousands of requests for information and education from people experiencing incontinence, healthcare professionals, and industry.

TCCF interacts with the media to increase public awareness and knowledge of incontinence and to encourage people to seek help. It also provides individuals with lists of specialists in their local area. TCCF initiated and now coordinates *Incontinence Awareness Month* in November of each year, promoting public and professional awareness-building and educational activities about incontinence around the country.

The Canadian Continence Foundation encourages and supports research to advance incontinence management/treatment.

Conflict of Interest Declarations

- a) We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:

The Canadian Continence Foundation has multiple sources of funding for programs and operations, and is supported by individual and corporate donations. Funding sources include: donations from individuals, healthcare professionals, and industry. TCCF does not receive any government funding.

Our relationship and interactions with pharmaceutical companies remains as transparent as possible and policy positions of the TCCF are developed with input from a large number of stakeholders. Corporate relationships are ongoing with the intention of achieving TCCF goals as they relate to patient support and education.

TCCF has currently received both restricted and unrestricted educational grants from the following health care companies Allergan, Astellas, Laborie, Tena - a Personal Care brand by SCA. These corporate sponsors are disclosed on The Canadian Continence Foundation's website.

- b. We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:
No conflicts.

2. Condition and Current Therapy Information

2.1 Information Gathering

The information provided was obtained through an online survey, which was completed by 68 respondents in February and March 2013. The online survey was then updated and revised in May 2014 and there were an additional 101 respondents up to June 10, 2014. The national survey was available in French and English.

Additional information was gathered through one-to-one telephone conversations with five patients between February 15 and March 20, 2013, and an additional 12 patients and caregivers between May 26 and June 6, 2014.

2.2 Impact of Condition on Patients

As described in TCCF's previous patient input submission in April 2013, incontinence means losing urine when you don't want to. Overactive bladder (OAB) affects approximately 15% of the adult population. Symptoms include urgency (*urgent sensation to empty the bladder*), usually with frequency (*8 or more void per 24h*) and nocturia (one or more void during the night), with or without urge incontinence (*leakage of urine usually associated with a sudden urge to urinate*).

Unfortunately, very few people talk to their doctor about their symptoms. According to the Canadian Urinary Bladder Survey, 16% of men and 33% of women over the age of 40 have symptoms of urinary incontinence (UI), but only 26% have discussed it with their doctor and this is a conservative estimate. A recent epidemiological survey that TCCF conducted in 2013 found that 36% of community dwelling women suffer from UI. This is further supported by a 2008 OHTAC report, where incontinence was noted as one in four major predictors for Long Term Care (LTC) admissions: falls and fall-related injuries, urinary incontinence, dementia, and social isolation. Incontinence also plays a significant role in the remaining three conditions.

As it pertains to overactive bladder, the aspects of this condition that are most important to control are urinary urgency and involuntary leakage of urine.

All patients surveyed and interviewed experienced symptoms and problems related to overactive bladder, all of which affected day-to-day living. In almost all cases, these symptoms and problems required limiting or modifying daily activities, such as not leaving the house as often as they would like (leading to isolation and depression), modifying diet and limiting drinking water and other beverages, planning trips to the bathroom, getting up in the night (also leading to depression), and wearing incontinence pads to prevent leaking.

Some of the survey responses by patients living with overactive bladder are the following:

- 82% of survey respondents and all patients interviewed said they experience urinary urgency and urge incontinence. This was by far the most significant issue that affected their quality of life. Over half of patients had to “toilet map” before going anywhere so as not to have an accident. Most described the fear of embarrassment from leaking or soaking through clothing as a common concern when leaving their homes.
- Over 58% of all patients also described urinary frequency and nocturia as problems that affect them every day. Over 56% of patients said their sleep was interrupted by having to get up and use the toilet during the night.
- Fear of odour is cited by 52% of patients as a worry in dealing with overactive bladder. Most patients said they worry about smelling like urine and one individual said they experienced a “loss of self esteem and sense of control of my life. My bladder controls every aspect of my day”, while another says they “desperately try to cross my legs to ‘keep it in’”.
- Managing overactive bladder also has financial consequences, with 35% of patients saying that buying incontinence supplies, such as pads or incontinence underwear, is quite costly.
- Over 20% of patients described activities they limit, such as going on trips, socializing, going to movies where you would sit for long periods of time, participating in outdoor activities such as skiing, hiking, biking for fear of not getting to the toilet in time.
- Over 20% of individuals with overactive bladder felt that it was compromising their work productivity, or affecting their ongoing ability to work given the urge incontinence, urinary urgency and frequency.
- Further, 34% of individuals had a decrease in sexual activity because of fear of leakage, odour or general embarrassment.
- Most often, patients described their desire to reduce urinary urgency and urge incontinence as symptoms to better control. For those who experienced interrupted sleep, this was also seen as a problem that if controlled, would have a positive impact on their quality of life.
- Most patients have tried other medications, in some cases have had surgery, do Kegel exercises and bladder training, however these treatments have had no sustained benefit.
- A number of individuals said they have to plan what they drink every day depending on what they need to get done at home or at work. Many patients described the feeling that people think they are ‘manufacturing’ their illness and exaggerating their symptoms, and that people dismiss their overactive bladder as nothing serious. One individual described “the endless preoccupation and seemingly endless tweaking of diet, balancing of exercise and bowel movements, planning out overnight visits and trying to get back to hiking”, as a fact of daily life managing overactive bladder.

2.3 Patients' Experiences with Current Therapy

All surveyed patients have had some kind of therapy for overactive bladder including medications (Detrol, Enablex and Vesicare most frequently mentioned, in addition to Oxybutynin and Botox), and behavioural treatment. Many patients had undergone surgery only to find symptoms returning after a period of time. Several patients interviewed by phone described overactive bladder as the result of some other chronic illness, such as MS and epilepsy, stroke and lupus. In most cases, patients said the treatments were not effective at controlling their symptoms and often, side effects such as constipation and dry mouth, were very difficult to tolerate. Many patients noted that their physicians did not prescribe new medications when available since they were not covered by public drug plans. The most frequently mentioned symptoms that patients hoped to control better were urinary urgency and urge incontinence (80.3%), relief from side effects of current treatments, and being able to sleep through the night.

- Over 63% of patients surveyed have been prescribed medication to treat overactive bladder, and yet more than half said their current treatments were not effective at controlling their symptoms.
- Nearly 50% of patients have been referred to a specialist/urologist and have tried various treatments including surgery, behavioural treatment and a number of medications, including Detrol, Enablex, Vesicare, Oxybutynin and Botox.
- The most common adverse effects experienced by patients taking current medications are dry mouth, followed by constipation, and blurred vision.
- Additionally, almost 50% of patients said they have stopped taking their medications because they weren't effective in treating the underlying issues and symptoms of overactive bladder.
- One patient noted that Detrol was not good at controlling urinary incontinence and so she stopped taking it.
- One patient noted that Vesicare was quite effective at controlling symptoms, but the side effect of severe dry mouth was intolerable. The patient would wake up nearly choking from being unable to swallow and would panic until they could take in enough water. This made for a very fretful sleep.
- Embarrassment and depression regarding daily management of symptoms was often reported in telephone conversations with patients.

2.4 Impact on Caregivers

Twenty-five caregivers responded to the national survey and two were contacted in telephone interviews. All are affected by the symptoms of caring for someone with overactive bladder.

- Half of caregivers are getting up often or always during the night when their family member goes to the bathroom.
- Over half of caregivers often or always have to help eliminate odours or clean up after "accidents", including doing laundry frequently or often needing to change their bed linens.
- Half of caregivers often or always have to help get their family member to the bathroom on time, and this can be a challenge, particularly when their spouse has other chronic conditions that limit mobility such as a stroke.
- One patient who lives with her daughter and family described that the family have to adjust to her frequent stops to urinate, and that her grandchildren tell her she uses the bathroom more often than they do. The patient finds this embarrassing and feels bad that her need to use the bathroom so often affects everyone in the family.
- Another patient said her husband is now used to taking much longer trips as a result of frequent stops to the bathroom.

- Most patients said their spouses, families, or caregivers are all very understanding and accommodating, but they still feel bad about having everyone adjust to the issues of managing overactive bladder. A few patients interviewed indicated that their family members feel that they may be exaggerating their symptoms and made comments like they “should be able to hold it”.

3. Information about the Drug Being Reviewed

3.1 Information Gathering

The information provided was obtained through an online survey, which was completed by a total of 169 respondents. The national survey was available in French and English. The online survey was updated and launched on May 21, with an additional 101 patients and caregivers completing the survey.

Additionally, information specific to the patient experience with Mirabegron (Myrbetriq) was gathered through one-to-one telephone conversations with 17 patients. The first wave of interviews and surveys were conducted and completed between February 15 and March 20, 2013 and included in the first submission to CDR in April 2013. An additional 10 patients and two caregivers were interviewed over the phone between May 26 and June 10, 2014.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

- a) Based on no experience using the drug:
Most patients had tried several medications over the years to control overactive bladder, and almost half of the group surveyed said they stopped taking their medication because it was not improving urinary urgency or incontinence. Patients were willing to tolerate side effects (including constipation, dry mouth and dry eyes) if a new drug would reduce urgency and frequency, and would help manage leakage. If the underlying symptoms were not addressed adequately, many stopped taking their medication.
- For patients who have not had experience with Mirabegron, 80.3% are hoping that this medication will better control their symptoms and close to 50% are hopeful that there will be fewer side effects than their current medications, especially dry mouth, constipation and dry eyes.
 - Several patients noted the desire to be able to sleep through the night, and not wake up their spouse/partner.
 - Another individual noted that they would like not to wear incontinence pads or have such frequent urge incontinence.
- b) Based on patients’ experiences with the new drug as part of a clinical trial or through a manufacturer’s compassionate supply:
All patients interviewed who had experience with Mirabegron found that their symptoms were controlled far better than on any previous therapy. In the words of one patient, it was “life changing to be on this drug and have it work so well.” Another commented that it was the first time they felt symptom-free.
- In all cases, patients who were on Mirabegron found it far better than Detrol and Vesicare in controlling symptoms.
 - One patient commented that it was the first time in years that she was sleeping through the night and was very disappointed when she couldn’t stay on the drug after the trial ended.

She said that since she's been off the drug she's gradually getting worse again and is not taking other medication since she found nothing had previously worked for her.

- Several patients commented that they no longer had to wear pads and both caregivers said they weren't getting up as often through the night.
- Another patient said she stopped leaking on Mirabegron but since she's been off the medication, she has gone back to wearing pads and is now constipated again from being on Vesicare.
- Patients without drug plan coverage noted the cost of the drug as being expensive but felt they had no choice since Mirabegron was providing them with symptom relief. Two patients also noted the cost of the drug and said it meant making other choices on fixed incomes in order to pay for Mirabegron.
- Several patients with drug plans still had to pay a portion of the cost but said it was worth it not to have to spend money on pads.

4. Additional Information