

Myrbetriq® (mirabegron) – Expanded indication

- On April 27, 2018, the FDA approved Astellas' [Myrbetriq \(mirabegron\)](#), for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in combination with the muscarinic antagonist [Vesicare® \(solifenacin\)](#).
 - Previously, Myrbetriq was approved for the treatment of OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency.
- The efficacy of Myrbetriq in combination with Vesicare was demonstrated in two, 12-week studies. In the first study, patients were randomized to placebo, Vesicare 5 mg, Myrbetriq 25 mg, Myrbetriq 50 mg, Vesicare 5 mg plus Myrbetriq 25 mg, or Vesicare 5 mg plus Myrbetriq 50 mg once daily. In the second study, patients were randomized to Vesicare 5 mg, Vesicare 10 mg, or Vesicare 5 mg plus Myrbetriq 25 mg (increased to 50 mg at 4 weeks) once daily.
 - In the first study, the difference in the number of incontinence episodes per 24 hours were -0.25 (95% CI: -0.49, -0.01) and -0.34 (95% CI: -0.58, -0.10) for the combination Myrbetriq 25 mg group vs. Vesicare group and vs. Myrbetriq 25 mg group, respectively, and -0.20 (95% CI: -0.44, 0.04) and -0.23 (95% CI: -0.47, 0.01) for the combination Myrbetriq 50 mg group vs. Vesicare group and vs. Myrbetriq 50 mg group, respectively.
 - In the first study, the difference in the number of micturitions per 24 hours were -0.29 (95% CI: -0.57, -0.01) and -0.39 (95% CI: -0.67, -0.11) for the combination Myrbetriq 25 mg group vs. Vesicare group and vs. Myrbetriq 25 mg group, respectively, and -0.48 (95% CI: -0.78, -0.21) and -0.58 (95% CI: -0.84, -0.28) for the combination Myrbetriq 50 mg group vs. Vesicare group and vs. Myrbetriq 50 mg group, respectively.
 - In the second study, the change from baseline in the number of incontinence episodes per 24 hours was -1.53 for the Vesicare 5 mg group vs. -1.80 for the combination Myrbetriq/Vesicare group (difference: -0.26 [95% CI: -0.47, -0.05]).
- The recommended starting doses for combination treatment are Myrbetriq 25 mg orally once daily and Vesicare 5 mg orally once daily. Based on individual patient efficacy and tolerability, the Myrbetriq dose may be increased to 50 mg once daily after 4 to 8 weeks.
 - The recommended starting dose of Myrbetriq monotherapy is 25 mg orally once daily with or without food. Myrbetriq 25 mg is effective within 8 weeks. Based on individual patient efficacy and tolerability the dose may be increased to 50 mg once daily.