For your patients with overactive bladder (OAB)

Rethinq OAB Treatment

Myrbetriq is a β_3–adrenergic agonist indicated for patients with OAB symptoms of urge urinary incontinence, urgency, and urinary frequency.[1]

As of April 2017, Myrbetriq is covered for **89%** of lives on Medicare Commercial plans.[2]*†

*Not a guarantee of coverage. Please verify coverage and updated information with the plan sponsors. Information subject to change without notice.

†By Medicare covered lives (39,751,085); Plan types: Medicare MA, Medicare PDP. Source: Business One Technologies, April 2017.

Mechanism of Action

Think β_3. Think Myrbetriq.

The first and only FDA–approved β_3–adrenergic agonist.

Myrbetriq is not an antimuscarinic agent.[1] It targets a different receptor signaling pathway— the β_3–adrenergic receptor (AR) pathway.

- Overactive bladder (OAB) is characterized by involuntary contraction of the detrusor muscle during the storage phase.[3]
- Myrbetriq relaxes the detrusor smooth muscle during the storage phase of the urinary bladder fill–void cycle by activation of the β_3–AR.

As a result, bladder capacity is increased.

- Mirabegron is an agonist of the human β_3–AR as demonstrated by in vitro laboratory experiments using the cloned human β_3–AR.[1]

ASTELLAS 2003

- Although mirabegron showed very low intrinsic activity for cloned human β_1–AR and β_2–AR, results in humans indicate that β_1–AR stimulation occurred at a mirabegron dose of 200 mg.[1]

See how Myrbetriq targets the β_3–AR pathway.

Watch MOA

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Need Myrbetriq samples for your patients? Submit your request here.

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Get materials on overactive bladder (OAB) for your patients.

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The Momentum Program offers money-saving opportunities for eligible patients.‡

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‡Subject to eligiblity. Restrictions may apply.

Behavioral therapies may be combined with **pharmacologic management** as a first-line treatment option for **OAB**, according to **AUA/SUFU** guidelines[4]

Adapted from AUA/SUFU (American Urological Association/Society of Urodynamics, Female Pelvic Medicine, & Urogenital Reconstruction) guidelines.

Efficacy Summary

Tap to expand

\+ Study Design[1]

Tap to expand

\+ Efficacy evaluated in three 12-week, double-blind, placebo-controlled Phase III studies[1]

Safety Profile

Tap to expand

\+ Safety evaluated in three 12-week, double-blind, placebo-controlled Phase III studies[1]**

Tap to expand

\+ Safety evaluated in a 1-year, randomized, fixed-dose, double-blind, active-controlled study[1††]

**In Studies 1, 2, and 3, Myrbetriq was evaluated for safety in 2736 patients. Study 1 also included an active control. For the combined Studies 1, 2, and 3, 432 patients received Myrbetriq 25 mg, 1375 received Myrbetriq 50 mg, and 929 received Myrbetriq 100 mg once daily.
††Myrbetriq was also evaluated for safety in 1632 patients who received Myrbetriq 50 mg once daily (n=812 patients) or Myrbetriq 100 mg (n=820 patients) in a 1–year study in patients with OAB (Study 4). • Of these patients, 731 received Myrbetriq in a previous 12–week study. • In Study 4, 1385 patients received Myrbetriq continuously for at least 6 months, 1311 patients received Myrbetriq for at least 9 months, and 564 patients received Myrbetriq for at least 1 year.

Dosing

Convenient, once-daily oral therapy

The recommended starting dose of Myrbetriq® (mirabegron) is 25 mg orally, once daily[1]

- Myrbetriq 25 mg can be effective within 8 weeks.[1]
- Based on individual patient efficacy and tolerability, the dose may be increased to 50 mg, once daily.[1]
- Myrbetriq can be taken with or without food.[1]
- Myrbetriq should be taken with water, swallowed whole, and should not be chewed, divided, or crushed.[1]

There is no generic equivalent to Myrbetriq

Dose adjustments in special populations[1]

- The daily dose of Myrbetriq should not exceed 25 mg once daily in the following populations:
  - Patients with severe renal impairment (CL_{cr} 15 to 29 mL/min or eGFR 15 to 29 mL/min/1.73 m^2).
  - Patients with moderate hepatic impairment (Child–Pugh Class B).
-

Myrbetriq is not recommended for use in patients with end-stage renal disease (ESRD) or in patients with severe hepatic impairment (Child–Pugh Class C).

- No dose adjustment is necessary for the elderly.
- The safety and effectiveness of Myrbetriq in pediatric patients have not been established.

INDICATIONS AND USAGE

Myrbetriq® (mirabegron) is a beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

IMPORTANT SAFETY INFORMATION

Myrbetriq is contraindicated in patients who have known hypersensitivity reactions to mirabegron or any component of the tablet.

Myrbetriq can increase blood pressure. Periodic blood pressure determinations are recommended, especially in hypertensive patients. Myrbetriq is not recommended for use in severe uncontrolled hypertensive patients (defined as systolic blood pressure ≥ 180 mm Hg and/or diastolic blood pressure ≥ 110 mm Hg).

Urinary retention in patients with bladder outlet obstruction (BOO) and in patients taking antimuscarinic medications for the treatment of OAB has been reported in postmarketing experience in patients taking mirabegron. A controlled clinical safety study in patients with BOO did not demonstrate increased urinary retention in Myrbetriq patients; however, Myrbetriq should be administered with caution to patients with clinically significant BOO. Myrbetriq should also be administered with caution to patients taking antimuscarinic medications for the treatment of OAB.

Angioedema of the face, lips, tongue and/or larynx has been reported with Myrbetriq. In some cases angioedema occurred after the first dose. Cases of angioedema have been reported to occur hours after the first dose or after multiple doses. Angioedema associated with upper airway swelling may be life threatening. If involvement of the tongue, hypopharynx, or larynx occurs, promptly discontinue Myrbetriq and initiate appropriate therapy and/or measures necessary to ensure a patent airway.

Since Myrbetriq is a moderate CYP2D6 inhibitor, the systemic exposure to CYP2D6 substrates such as metoprolol and desipramine is increased when co-administered with Myrbetriq. Therefore, appropriate monitoring and dose adjustment may be necessary, especially with narrow therapeutic index drugs metabolized by CYP2D6, such as thioridazine, flecainide, and propafenone.

In clinical trials, the most commonly reported adverse reactions (> 2% and > placebo) for Myrbetriq 25 mg and 50 mg versus placebo, respectively, were hypertension (11.3%, 7.5% vs 7.6%), nasopharyngitis (3.5%, 3.9% vs 2.5%), urinary tract infection (4.2%, 2.9% vs 1.8%), and headache (2.1%, 3.2% vs 3.0%).

In postmarketing experience, the following events have also occurred: constipation, diarrhea, and dizziness.

Please see accompanying complete Prescribing Information for Myrbetriq® (mirabegron)

REFERENCES

1. Myrbetriq [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc. 2. Astellas Pharma US, Inc. Data on File. 3. Chu FM, Dmochowski R. Pathophysiology of overactive bladder. *Am J Med.* 2006;119(3):3S–8S. 4. Gormley EA, Lightner DJ, Burgio KL, et al. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU guideline. Linthicum, MD: American Urological Association Education and Research, Inc.; 2014:1–57. 5. Khullar V, Amarenco G, Angulo JC, et al. Efficacy and tolerability of mirabegron, a β_3-adrenoceptor agonist, in patients with overactive bladder: results from a randomised European–Australian phase 3 trial. *Eur Urol.* 2013;63:283–295.

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