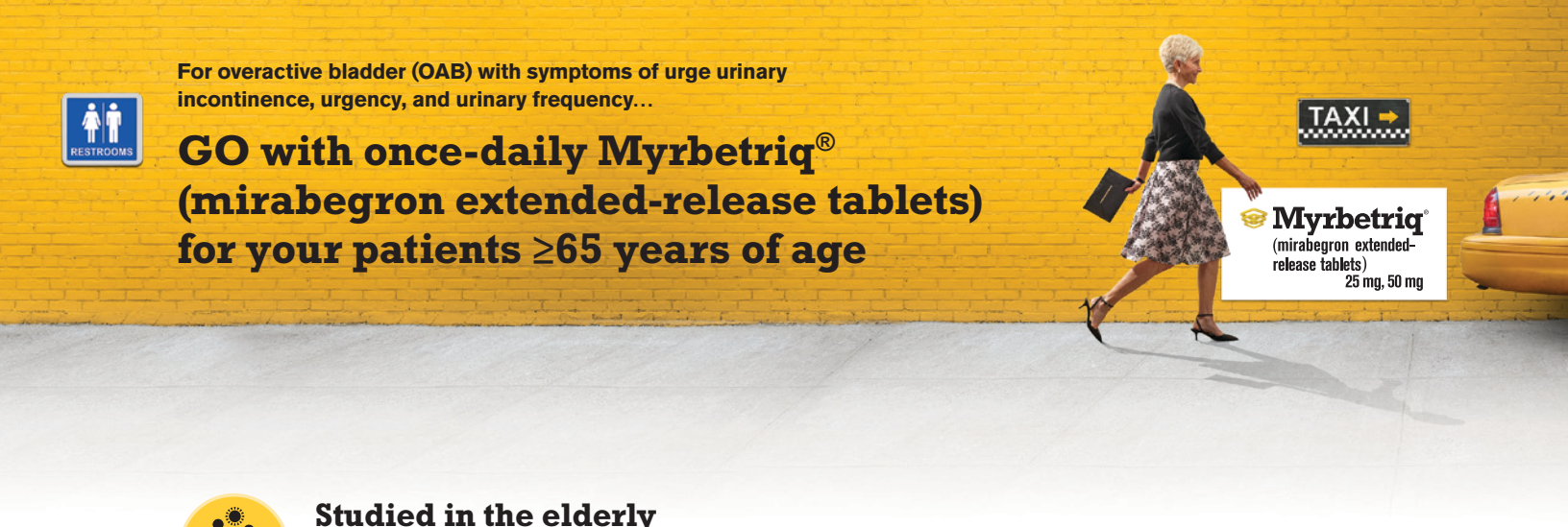


For overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency…

GO with once-daily Myrbetriq® (mirabegron extended-release tablets) for your patients ≥65 years of age

Studied in the elderly

Myrbetriq has been studied in 2029 patients ≥65 years of age.[1*]

*Of 5648 patients who received Myrbetriq monotherapy in the Phase II and III studies for OAB, 2029 (35.9%) were 65 years of age or older, and 557 (9.9%) were 75 years of age or older.

Safety and efficacy evaluated in elderly patients

No overall differences in safety or effectiveness were observed between patients <65 years and those ≥65 years of age in the Phase II and III studies of Myrbetriq.[1]

Similar pharmacokinetics

The pharmacokinetics of Myrbetriq were similar in elderly and younger volunteers.[1†]

†The C_{max} and area under curve (AUC) of Myrbetriq following multiple oral doses in elderly volunteers (≥65 years) were similar to those in younger volunteers (18 to 45 years).

No dose adjustment is required based on age[1]

Prospective Phase IV trial published 2/2020

The efficacy, safety, and tolerability of Myrbetriq was studied in the PILLAR trial—the first prospective study of Myrbetriq in adults ≥65 years of age with wet OAB symptoms.[2]

INDICATIONS AND USAGE

MYRBETRIQ® (mirabegron extended-release tablets) is indicated for the treatment of overactive bladder (OAB) in adult patients with symptoms of urge urinary incontinence, urgency, and urinary frequency.

IMPORTANT SAFETY INFORMATION

MYRBETRIQ is contraindicated in patients with known hypersensitivity reactions to mirabegron or any inactive ingredients of the tablet.

MYRBETRIQ can increase blood pressure in adults. 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). Worsening of pre-existing hypertension was reported infrequently in patients taking MYRBETRIQ.

In patients taking MYRBETRIQ, urinary retention has been reported in patients with bladder outlet obstruction (BOO) and in patients taking muscarinic antagonist medications for the treatment of OAB. A controlled clinical safety study in patients with BOO did not demonstrate increased urinary retention in patients treated with mirabegron; however, MYRBETRIQ should still be administered with caution to patients with clinically significant BOO. For example, monitor these patients for signs and symptoms of urinary retention. MYRBETRIQ should also be administered with caution to patients taking muscarinic antagonist medications for the treatment of OAB.

Please see additional Important Safety Information on page 2.
Please see accompanying complete Prescribing Information for Myrbetriq® (mirabegron extended-release tablets)

Myrbetriq in patients ≥65 years of age (PILLAR study)

The efficacy, safety, and tolerability of Myrbetriq was studied in the PILLAR trial—the first prospective study of Myrbetriq in patients ≥65 years of age with wet OAB symptoms.[2]

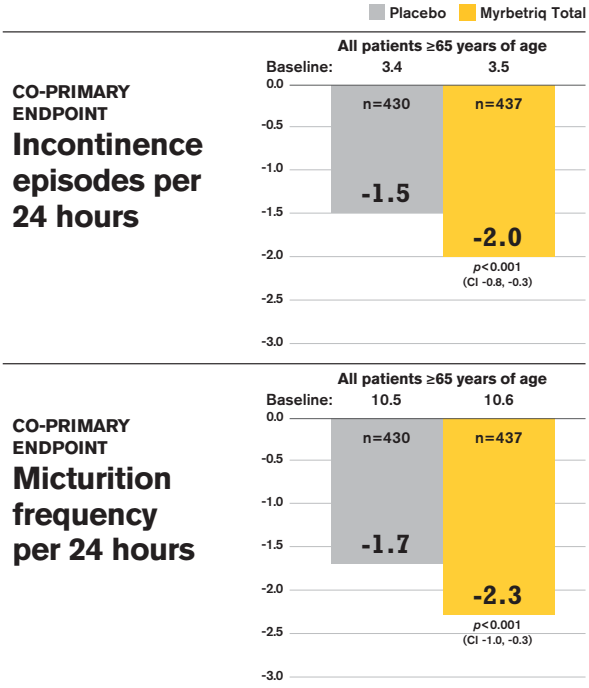
STUDY DESIGN AND PATIENT POPULATION[2]

A double-blind, randomized, placebo-controlled, parallel-group, multicenter Phase IV study of community-dwelling patients ≥65 years of age who entered a 2-week placebo run-in period, during which time a 3-day micturition training diary was completed prior to being randomized to 1 of 2 treatment groups for 12 weeks. Entry criteria required that patients have symptoms of wet OAB for ≥3 months with ≥1 incontinence episode, ≥3 urgency episodes, and an average of ≥8 micturitions episodes per day. Those who entered the 12-week treatment period were randomized 1:1 and stratified by age. Patients were randomized to Myrbetriq 25 mg or placebo and were given the option to increase to 50 mg at Week 4 or Week 8 based on individual efficacy, tolerability, and investigator discretion. Patients completed 3-day micturition diaries immediately before study visits at Week 4, 8, and 12.

This study was designed to detect a difference between placebo and total Myrbetriq groups and not for each individual dosing group.

EFFICACY RESULTS[2]

Adjusted mean change from baseline to EoT



CI=confidence interval; EoT=end of treatment.

SAFETY AND TOLERABILITY[2]

Percent of patients with treatment-emergent adverse events (TEAEs)* who received ≥1 dose of study medication

	Placebo (%)	Myrbetriq 25 mg (%)	Myrbetriq 50 mg (%)
Number of Patients	**442**	**226**	**219**
≥1 TEAE	39	44	50
Drug-related TEAEs†	13	21	17
Serious TEAEs	2.7	3.1	3.7
Serious drug-related TEAEs†	0.45	0	0
TEAEs leading to discontinuation	3.2	3.5	2.7
Drug-related TEAEs leading to discontinuation†	1.6	2.7	1.8
Cardiac disorders	1.1	0.88	3.2
Most frequent TEAEs‡			
Urinary tract infection§	7.0	7.1	4.1
Headache	2.7	6.6	3.7
Diarrhea	1.4	4.9	0.91
Fatigue	3.2	2.7	1.8
Upper respiratory tract infection	2.3	1.3	3.2
Nausea	1.4	3.1	0.46
Dizziness	1.6	0.44	2.3
Nasopharyngitis	2.3	1.3	0.91

*Treatment-emergent adverse event (TEAE) is defined as an adverse event which started or worsened in the period from first double-blind medication intake until 30 days after the last double-blind medication intake.

†Possible or probable, as assessed by the investigator, or where relationship was missing.

‡Preferred term; affecting ≥2% of any treatment group.

§*Escherichia* urinary tract infection, streptococcal urinary tract infection, urinary tract infection, or urinary tract infection bacterial.

IMPORTANT SAFETY INFORMATION (cont'd)

Angioedema of the face, lips, tongue, and/or larynx has been reported with MYRBETRIQ. In some cases, angioedema occurred after the first dose. Cases 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 provide appropriate therapy and/or measures necessary to ensure a patent airway.

Since MYRBETRIQ is a moderate CYP2D6 inhibitor, the systemic exposure to CYP2D6 substrates 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.

In clinical trials, the most commonly reported adverse reactions in adults (> 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: atrial fibrillation, nausea, constipation, diarrhea, and dizziness.

Please see accompanying complete Prescribing Information for Myrbetriq® (mirabegron extended-release tablets)

References: 1. Myrbetriq [package insert]. Northbrook, IL: Astellas Pharma US, Inc. **2.** Wagg A, Staskin D, Engel E, Herschorn S, Kristy RM, Schermer CR. Efficacy, safety, and tolerability of mirabegron in patients aged ≥65yr with overactive bladder wet: a phase IV, double-blind, randomised, placebo-controlled study (PILLAR). Eur Urol 2020;77(2):211-20.

Myrbetriq® (mirabegron extended-release tablets) 25 mg, 50 mg

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Prescribing Information

Front

Back

8.5”

11”

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Prospective Phase IV trial published 2/2020

The efficacy, safety, and tolerability of Myrbetriq was studied in the PILLAR trial—the first prospective study of Myrbetriq in adults ≥65 years of age with wet OAB symptoms.2

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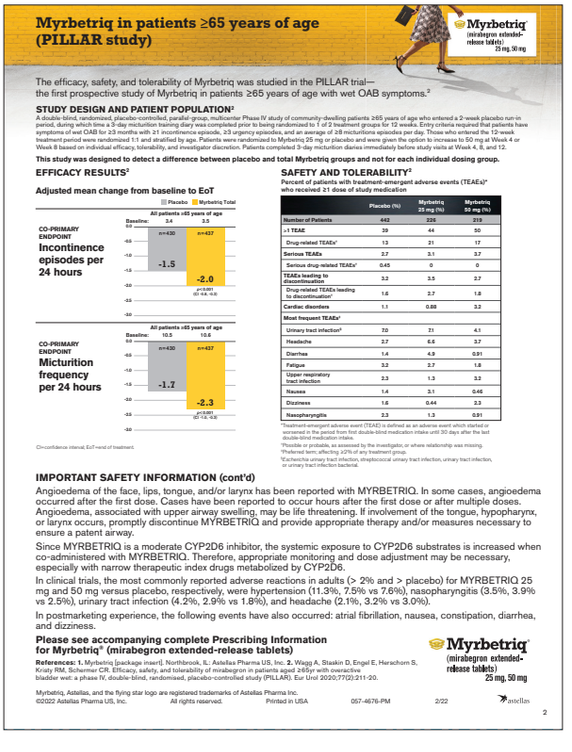

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2