

Safety and tolerability of overactive bladder treatments using a large integrated database of mirabegron clinical studies involving >10,000 overactive bladder patients

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Key study outcomes

DRUG-RELATED TEAE FREQUENCY

Frequency of drug-related TEAEs slightly higher for antimuscarinics than for mirabegron

DRY MOUTH

More frequent for antimuscarinics than for mirabegron

CARDIOVASCULAR AND URINARY RETENTION TEAEs

Low frequency in all groups

LARGE IDB

Reaffirms the safety profiles of mirabegron, solifenacin and tolterodine

OBJECTIVE

To assess safety and tolerability of mirabegron and antimuscarinics using a large integrated database (IDB) of data from patients with OAB

METHODS

- Included all adults who received ≥1 dose of monotherapy study drug (placebo, mirabegron 25 mg/50 mg, solifenacin 2.5 mg/5 mg/10 mg, tolterodine ER 4 mg) for overactive bladder (OAB) symptoms in 10 double-blind, 12-week, Phase II-IV global mirabegron studies¹⁻¹⁰
- Data presented for aggregated treatment groups (total mirabegron, total antimuscarinics, placebo)
- Treatment-emergent adverse events (TEAEs) defined as any adverse event observed after starting study drug
- Good Clinical Practice guidelines and Principles of Declaration adhered to; written informed consent obtained

Demographic characteristics by treatment group (SAF)			
Category/statistic, n (%)	Placebo (n=3018)	Total Mirabegron (n=5244)	Total Antimuscarinics (n=2999)
Female	2282 (75.6)	3953 (75.4)	2232 (74.4)
Race, n	3014	5235	2995
White	1870 (62.0)	3751 (71.7)	2143 (71.6)
Black/African American	98 (3.3)	128 (2.4)	19 (0.6)
Asian	1032 (34.2)	1328 (25.4)	826 (27.6)
Other	14 (0.5)	28 (0.5)	7 (0.2)
Mean age, years ± SD	57.9 ± 13.4	57.4 ± 13.5	57.2 ± 13.6
Type of OAB at screening			
Urgency incontinence only*	1353 (44.8)	2403 (45.8)	1352 (45.1)
Mixed stress/urgency incontinence	867 (28.7)	1436 (27.4)	653 (21.8)
Frequency/urgency without incontinence	796 (26.4)	1403 (26.8)	992 (33.1)
Unknown	2 (0.1)	2 (0.0)	2 (0.1)
Prior OAB medication history			
Discontinued due to lack of efficacy	642 (51.0)	1908 (69.0)	1325 (77.6)
Discontinued due to poor tolerability	242 (19.2)	502 (18.2)	316 (18.5)
Hypertensive at Baseline	774 (25.6)	1447 (27.6)	821 (27.4)

*With urgency as a predominant factor
SAF=Safety Analysis Set; SD=standard deviation



11,261 PATIENTS

75% of patients were female and the majority were white with a mean age of 57.5 years



OAB SYMPTOMS

6-7% more patients receiving antimuscarinics had frequency/urgency without incontinence and 5-7% fewer had mixed incontinence vs mirabegron and placebo



PRIOR OAB TREATMENT HISTORY

Discontinuations were 3-4 times more frequent due to lack of efficacy than to poor tolerability in all groups



DISCONTINUATIONS

Infrequent across all groups (9.5%, 8.3% and 11.4% for mirabegron, antimuscarinics, and placebo, respectively)



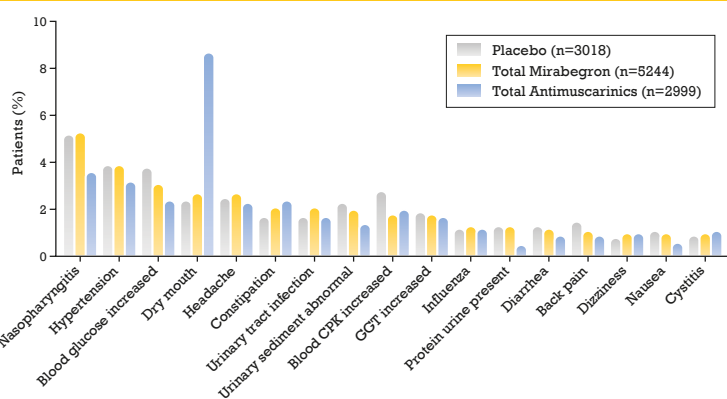
TEAE FREQUENCY

Similar across groups, although slightly more drug-related TEAEs for antimuscarinics (21.4%) vs mirabegron (17.0%)

Overview of TEAEs and treatment discontinuation status (SAF)

Category/statistic, n (%)	Placebo (n=3018)	Total Mirabegron (n=5244)	Total Antimuscarinics (n=2999)
Completed treatment	2674 (88.6)	4744 (90.5)	2749 (91.7)
TEAEs	1483 (49.1)	2366 (45.1)	1285 (42.8)
Drug-related TEAEs	511 (16.9)	894 (17.0)	641 (21.4)
Drug-related TEAEs leading to discontinuation	48 (1.6)	93 (1.8)	59 (2.0)
Serious TEAEs	53 (1.8)	77 (1.5)	40 (1.3)

Common TEAEs*



*TEAEs with ≥1% frequency in the Total Mirabegron or Total Antimuscarinics group
CPK=creatinine phosphokinase; GGT=gamma-glutamyltransferase



DRY MOUTH

More frequent for antimuscarinics (8.7%) vs mirabegron (2.7%) and placebo (2.4%)



CARDIOVASCULAR TEAEs

Low frequency of palpitations and tachycardia (<1% in all groups) and treatment-emergent hypertension (3.2-3.9% across groups)



URINARY RETENTION

<0.5% in all groups

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