DID YOU KNOW?

PharMerica®

Gemtesa (Vibegron)

BACKGROUND

Overactive bladder (OAB), characterized by hallmark symptoms of **increased urgency/frequency of urination, urge incontinence, and nocturia,** is estimated to affect approximately 13 million people in the United States. Prevalence is highest among older adults, affecting ≥50% nursing facility residents and ≥75% long-term care residents. While OAB is treatable, older adults are at increased risk of experiencing adverse effects of certain treatments that demonstrate anticholinergic properties.

Gemtesa, a beta-3 agonist, is an ideal treatment option for older adults with OAB

- No anticholinergic properties
- Offers simple once daily administration
- Can be crushed
- Less drug-drug interactions (does not interact with CYP2D6 metabolized meds)
- No warning against use in residents with hypertension

INDICATIONS

Overactive Bladder (OAB):

- with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults.
- with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia (BPH).

WARNINGS/PRECAUTIONS

Urinary Retention: especially in patients with bladder outlet obstruction and those taking antimuscarinic medications.
Angioedema: angioedema of the face and/or larynx has been reported with administration.

ADULT DOSING & ADMINISTRATION

Administer one 75mg tablet orally once daily.

- Give with or without food, followed by a glass of water.
- Tablets **may be crushed** and mixed with a tablespoon (~15 mL) of applesauce, taken immediately with a glass of water.

DOSE ADJUSTMENTS

- Renal: No dose adjustment recommended for patients with mild, moderate, or severe renal impairment. Avoid in ESRD with or without hemodialysis (lack of studies).
- Hepatic: No dose adjustment recommended for patients with mild to moderate hepatic impairment (Child-Pugh A and B). Avoid in severe impairment (Child-Pugh C) (lack of studies).

ADVERSE REACTIONS (ADRS)

Most common adverse reactions (≥2%) reported with Gemtesa were headache, urinary tract infection, nasopharyngitis, diarrhea, nausea, and upper respiratory tract infection.

BLOOD PRESSURE CONSIDERATIONS

Gemtesa Is the **first and only beta-3 agonist without a blood pressure warning on its product label.** In a 4-week, randomized, placebo-controlled, ambulatory BP study in OAB patients (n=200), daily treatment with Gemtesa 75mg was **not associated with clinically significant changes in BP.**

DRUG-DRUG INTERACTIONS (DDIS)

Digoxin is the single drug product identified in the label regarding DDIs. Increase frequency of digoxin serum level monitoring before, during and after OAB treatment with Gemtesa.

Evidence-Based Medicine – Safety & Efficacy

OAB in Adults

Safety, efficacy, and tolerability of Gemtesa treatment was gathered through the 2020 EMPOWUR study (12-week, randomized, double-blind clinical trial). Individuals with existing OAB symptoms for ≥3 months and an average of at least 8 micturitions/day were randomized to Gemtesa 75mg, tolterodine ER 4mg, or placebo. Co-primary endpoints for the study were change from baseline in average daily number of micturitions and average daily number of urge urinary incontinence (UUI) episodes at week 12.

Of 1,518 participants, 90.4% completed the trial, with the following results:

- **Gemtesa (n=547): Micturition decreased by 1.8 episodes/day, UUI episodes decreased by 2.**
- Placebo (n=540): Micturition decreased by 1.3 episodes/day, UUI episodes decreased by 1.4.
- Tolterodine ER (n=431): Micturition decreased by 1.6 episodes/day, UUI episodes decreased by 1.8
- **Gemtesa was also statistically significantly superior to placebo for key secondary measures including number of urgency episodes, volume per micturition and proportion of incontinent patients, with a ≥75% reduction in urge incontinence episodes overall.**

OAB in Adult Males with BPH

Efficacy and safety of Gemtesa in adult males with OAB and BPH is supported by the 2024 COURAGE study (24 week, double-blind, randomized, placebo-controlled trial). Men ≥45 years of age with persistent OAB symptoms (≥8 micturitions & ≥3 urgency episodes per day) for ≥2 months and previously diagnosed BPH treated with a stable dose of an a-blocker (with or without a 5a-reductase inhibitor), were randomized to either Gemtesa 75mg daily or placebo. Co-primary endpoints for the study were change from baseline in average daily number of micturitions and average daily number of UUI episodes at week 12.

Of 1,105 participants, 87.3% completed the trial, with the following results:

- **Gemtesa (n=551): Micturition decreased by 2.04 episodes/day, UUI episodes decreased by 2.88.**
- Placebo (n=553): Micturition decreased by 1.3 episodes/day, UUI episodes decreased by 1.93.
- **Gemtesa use was associated with 2x increased urine output vs an alpha blocker alone (Gemtesa - 25.63 mL; Placebo - 10.56 mL).**

Ref: Urinary Incontinence – StatPearls – NCBI Bookshelf

This QRG is abridged to highlight clinical information for consultant pharmacists.
Please refer to Gemtesa's product label for more comprehensive prescribing information.