GEMTESA® (vibegron) 75 mg tablets

GEMTESA is covered on the TRICARE® Uniform Formulary for ~9.5 million beneficiaries[1,*]

GEMTESA	
Formulary Tier[2]	**Uniform Formulary** Covered
Co-Pay[3]	**Military treatment facility** (up to 30 days) Active duty $0, Non-active $0 **Retail** (up to a 1-month supply) Active duty $0, Non-active duty $43 **Mail order** (up to a 3-month supply) Active duty $0, Non-active duty $38
Standard Prior Authorization (PA) Criteria† for β_3 class[2]	**PA Required** Tried and failed behavioral interventions. Failure of one T1 anticholinergic with exemption for CNS AE or risk of CNS AE

AE=adverse event, CNS=central nervous system.
*Coverage status and number of beneficiaries updated December 2023.
†This does not include all PA requirements. Please see the full list of PA criteria in your TRICARE coverage policy.

Available in 30- and 90-day supply

Product images are not actual size.

INDICATIONS AND USAGE

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

GEMTESA is contraindicated in patients with known hypersensitivity to vibegron or any components of GEMTESA. Hypersensitivity reactions, such as angioedema, have occurred.

WARNINGS AND PRECAUTIONS

Urinary Retention

Urinary retention has been reported in patients taking GEMTESA. The risk of urinary retention may be increased in patients with bladder outlet obstruction and also in patients taking muscarinic antagonist medications for the treatment of OAB. Monitor patients for signs and symptoms of urinary retention, particularly in patients with bladder outlet obstruction and patients taking muscarinic antagonist medications for the treatment of OAB. Discontinue GEMTESA in patients who develop urinary retention.

Please see next page for additional Important Safety Information and accompanying full Prescribing Information.

PRESCRIBE GEMTESA FOR OAB SYMPTOM RELIEF[4]

THERE IS ONLY ONE GEMTESA–NO GENERIC SUBSTITUTE

GEMTESA IS THE FIRST AND ONLY β_3-AGONIST WITH[4]:

Efficacy data for all 3 key OAB symptoms in its label

vs placebo at 12 weeks[5]*

- The 3 key symptoms of OAB are **urgency, frequency, and urge urinary incontinence**[5]

One dose, no titration

- Once-daily 75 mg dose with no titration, to be taken with or without food, and swallowed whole with a glass of water
- In adults, GEMTESA tablets may be crushed, mixed with a tablespoon (~15 mL) of applesauce, and taken immediately with a glass of water

No blood pressure (BP) warning in its label[6-8]

- No clinically significant impact on blood pressure†‡

No CYP2D6 drug–drug interactions

- Digoxin drug interaction was identified with GEMTESA. Measure serum digoxin concentrations before initiating GEMTESA. Monitor serum digoxin concentrations to titrate digoxin dose to desired clinical effect. Continue monitoring digoxin concentrations upon discontinuation of GEMTESA and adjust digoxin dose as needed

*The efficacy of GEMTESA was evaluated in a pivotal 12-week, double-blind, randomized, placebo- and active-controlled trial in patients with OAB (urgency, urinary frequency, and urge urinary incontinence). For study entry, patients had to have symptoms of OAB for at least 3 months with an average of 8 or more micturitions per day and at least 1 urge urinary incontinence episode per day, or an average of 8 or more micturitions per day and an average of at least 3 urgency episodes per day. A total of 1,515 patients received at least 1 daily dose of placebo (n=540), GEMTESA 75 mg (n=545), or an active-control treatment (n=430). The majority of patients were Caucasian (78%) and female (85%) with a mean age of 60 (range 18 to 93) years.[6]

†In a 12-week pivotal study, hypertension rates for OAB patients taking GEMTESA (n=545) were 1.7% vs 1.7% with placebo (n=540). Increased BP rates were 0.7% with GEMTESA vs 0.9% with placebo.[7]

‡In a 4-week, randomized, placebo-controlled, ambulatory BP study in OAB patients (n=200), GEMTESA 75 mg was not associated with clinically significant changes in BP. Mean age 59 years; 75% female. At baseline: 35% of subjects had preexisting hypertension; 29% of subjects were taking at least 1 concomitant antihypertensive medication.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Angioedema

Angioedema of the face and/or larynx has been reported with GEMTESA. Angioedema has 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, immediately discontinue GEMTESA and provide appropriate therapy and/or measures necessary to ensure a patent airway.

ADVERSE REACTIONS

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

Please see full Prescribing Information.

References: 1. MMIT September 2024 TRICARE Department of Defense formulary data. **2.** Department of Defense. Department of Defense Pharmacy and Therapeutics Committee recommendations from the August 2022 meeting. **3.** Gemtesa 75 mg, Tablet. Open Enrollment - Pharmacy Benefit Plans. Published January 17, 2024. Accessed January 17, 2024. https://www.express-scripts.com/frontend/open-enrollment/tricare/fst/#/formularyPricing/results **4.** GEMTESA. Prescribing Information. Marlborough, MA; Sumitomo Pharma America; 2024. **5.** Edmondson SD, Zhu C, Kar NF, et al. Discovery of vibegron: a potent and selective β_3 adrenergic receptor agonist for the treatment of overactive bladder. *J Med Chem.* 2016;59(2):609-623. doi:10.1021/acs.jmedchem.5b01372. **6.** Staskin D, Frankel J, Varano S, Shortino D, Jankowich R, Mudd PN Jr. International phase III, randomized, double-blind, placebo and active controlled study to evaluate the safety and efficacy of vibegron in patients with symptoms of overactive bladder: EMPOWUR. *J Urol.* 2020;204(2):316-324. doi:10.1097/JU.0000000000000807. **7.** Data on file. Sumitomo Pharma America, Inc. **8.** Weber MA, Haag-Molkenteller C, King J, Walker A, Mudd PN Jr, White WB. Effects of vibegron on ambulatory blood pressure in patients with overactive bladder: results from a double-blind, placebo-controlled trial. *Blood Press Monit.* 2022;27(2):128-134. doi:10.1097/MBP.0000000000000572.

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