GEMTESA® (vibegron) 75 mg tablets

PRESCRIBE GEMTESA® FOR OVERACTIVE BLADDER (OAB) SYMPTOM RELIEF[1]

THERE IS ONLY ONE GEMTESA– NO GENERIC SUBSTITUTE

GEMTESA IS THE FIRST AND ONLY β_3-AGONIST WITH[1]:

Efficacy data for all 3 key OAB symptoms in its label

vs placebo at 12 weeks[2*]

- The 3 key symptoms of OAB are **urgency, frequency, and urge urinary incontinence**[2]

No blood pressure (BP) warning in its label[3-5]

- No clinically significant impact on BP[†‡]

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

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

*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.[4]

†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.[3]

‡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.

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.

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 accompanying full Prescribing Information.

UNRESTRICTED ACCESS FOR THE MAJORITY OF PATIENTS WITH OAB NATIONWIDE*

*All formulary data and access criteria are provided by the Managed Markets Insights & Technology, LLC, database as of January 2025.

AFFORDABLE ACCESS TO GEMTESA®

Commercially Insured Patients May Save With the GEMTESA Simple Savings Program†

For maximum savings
ELIGIBLE PATIENTS MAY PAY AS LITTLE AS **$0** per covered **90-DAY** prescription

OR · Eligible patients may pay as little as $10 a month for each covered 30-day prescription

OR · Eligible patients whose insurance does not cover GEMTESA may pay as little as $95 a month

†Restrictions and and maximum saving limits apply. Offers not valid for patients participating in Medicare, Medicaid, or other government healthcare programs. Programs are subject to change. See full Terms, Conditions, and Eligibility Criteria at GEMTESA.com/card.

Costs for **Medicare Part D** Prescriptions May Be Lower and More Predictable[6-9]‡,¶

Lower annual patient out-of-pocket (OOP) max

$2,000 for all covered drugs

If patient reaches OOP max

$0 Copay

Medicare Prescription Payment Plan

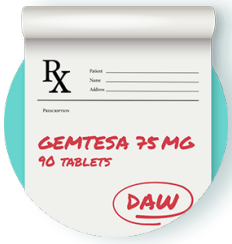
Patient can opt in to split OOP into monthly installments

‡Time frame to reach the $2,000 OOP maximum and begin paying $0 for covered prescriptions depends on individual plan benefits and monthly medication costs.
¶Monthly payments may vary based on individual plan design and when the patient opts in to the Medicare Prescription Payment Plan.

Broad support to help simplify access to GEMTESA

covermymeds® | GoodRx

Help ensure your patients get the OAB medication you have chosen



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

This resource is provided for informational purposes only. Contact your patients' health or Part D plans directly for more information about their prescription drug benefits. Sumitomo Pharma America makes no guarantees of coverage or reimbursement.

References: 1. GEMTESA. Prescribing Information. Marlborough, MA; Sumitomo Pharma America; 2024. **2.** Edmondson SD, Zhu C, Kar NF, et al. Discovery of vibegron: a potent and selective 3 adrenergic receptor agonist for the treatment of overactive bladder. *J Med Chem.* 2016;59(2):609-623. doi:10.1021/acs.jmedchem.5b01372. **3.** Data on file. Sumitomo Pharma America, Inc. **4.** 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. **5.** 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. **6.** Inflation Reduction Act, Pub. L. No. 117-169, 2022. **7.** HHS.gov. Biden-Harris administration releases final part two guidance to help people with Medicare prescription drugcoverage manage prescription drug costs. July 16, 2024. Accessed October 25, 2024. https://www.hhs.gov/about/news/2024/07/16/biden-harris-administration-releases-final-part-two-guidance-help-people-medicare-prescription-drug-coverage-manage-prescription-drug-costs.html **8.** Centers for Medicare & Medicaid Services. Medicare Prescription Payment Plan: final part one guidance. February 29, 2024. Accessed October 25, 2024. https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-one-guidance.pdf **9.** Centers for Medicare & Medicaid Services. Form CMS-10882. Exhibit 1 likely to benefit notice FINAL. July 16, 2024. Accessed October 25, 2024. https://www.cms.gov/files/zip/medicare-prescription-payment-plan-model-materials.zip

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