Gemtesa (vibegron)

NEW PRODUCT SLIDESHOW

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Introduction

- **Brand name:** Gemtesa
- **Generic name:** Vibegron
- **Pharmacologic class:** Beta-3 adrenergic agonist
- **Strength and Formulation:** 75mg; tablets
- **Manufacturer:** Urovant Sciences, Inc.
- **How supplied:** Tabs—30, 90
- **Legal Classification:** Rx

Gemtesa


90 tablets
NDC 73336-075-90
Rx Only
GEMTESA®
(vibegron) tablets
75 mg
One Tablet • Once Daily
May be swallowed whole or crushed
30 tablets
NDC 73336-075-30
Rx Only
GEMTESA®
(vibegron) tablets
75 mg
One Tablet • Once Daily
May be swallowed whole or crushed

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Indication

- Treatment of **overactive bladder (OAB)** with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults.

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Dosage and Administration

- Swallow whole with water.
- Tablet may also be crushed, mixed with a tablespoon (approximately 15mL) of applesauce and taken immediately with water.
- 75mg once daily.

Considerations for Specific Populations

- **Pregnancy:** No available data for drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.
- **Nursing mothers:** No data on the presence of vibegron in human milk, effects on breastfed infant, or effects on milk production; consider benefits of breastfeeding along with mother's clinical need and potential adverse effects.
- **Pediatrics**: Not established.
- **Geriatrics**: No overall differences observed from younger adult patients.
- **Renal impairment**: Patients with eGFR <15mL/min/1.73 m^2 (with or without hemodialysis): not recommended.
- **Hepatic impairment**: Severe hepatic impairment (Child-Pugh C): not recommended.

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Contraindications

- Patients with known hypersensitivity to vibegron or any components of the product.

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Warnings and Precautions

- Increased risk of **urinary retention** especially in patients with bladder outlet obstruction and in patients taking antimuscarinic drugs for OAB.
- Monitor for signs and symptoms of urinary retention; discontinue if develops.

Interactions

- Potentiates digoxin; monitor serum digoxin levels prior to initiation, during, and after therapy (titrate and adjust dose as needed).

Adverse Reactions

- **Most common (≥2%)**: Headache, urinary tract infection, nasopharyngitis, diarrhea, nausea, upper respiratory tract infection.
- **Others**: Urinary retention, dry mouth, constipation, hot flush.

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Mechanism of Action

- **Vibegron** relaxes the detrusor smooth muscle during bladder filling by activating the beta-3 adrenergic receptor which increases bladder capacity.

Pharmacokinetics

- **Absorption**: Median time to maximum plasma concentration is 1 to 3 hours.
- **Effect of food**: No differences observed following administration of a high-fat meal.
- **Elimination**:
  - Effective half-life: 30.8 hours.
  - Following a radiolabeled dose, approx. 59% of dose (54% as unchanged) was recovered in feces and 20% (19% as unchanged) in urine.

Clinical Trials

- Approval based on the 12-week, double-blind, randomized, placebo-controlled, active-controlled phase 3 EMPOWUR trial (ClinicalTrials.gov: NCT03492281) that evaluated the efficacy and safety of Gemtesa in 1515 adults with OAB.
- Patients randomly assigned to receive Gemtesa 75mg (n=545), placebo (n=540), or active control treatment (n=430) once daily.
- **Coprimary endpoints** were change from baseline in average daily number of micturitions and average daily number of urge urinary incontinence (UUI) episodes at week 12.

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Clinical Trials

- **Patient demographics**
  - Patients had OAB symptoms for ≥3 months with an average of ≥8 micturitions per day and ≥1 UUI per day, or an average of ≥8 micturitions per day and an average of ≥3 urgency episodes per day.
  - Mean age: 60 years (range, 18 to 93).
  - 78% Caucasian; 85% Female.

Clinical Trials

- **Results at week 12**
  - *Average daily number of micturitions*: change from baseline of -1.8 for Gemtesa vs -1.3 for placebo (difference from placebo: -0.5; 95% CI, -0.8, -0.2; *P* <.001).
  - *Average daily number of UUI episodes*: change from baseline of -2.0 for Gemtesa vs -1.4 for placebo (difference from placebo: -0.6; 95% CI, -0.9, -0.3; *P* <.0001).

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Clinical Trials

- **Results at week 12**
  - *Average daily number of "need to urinate immediately" (urgency) episodes*: change from baseline of -2.7 for Gemtesa vs -2.0 for placebo (difference from placebo: -0.7; 95% CI, -1.1, -0.2; *P* =.002).
  - *Average volume voided (mL) per micturition*: change from baseline of 23mL for Gemtesa vs 2mL for placebo (difference from placebo: 21; 95% CI, 14-28; *P* <.0001).

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/gemtesa/