HEALTHDIRECT PHARMACY SERVICES

Product Focus

Gemtesa® (Vibegron)

Description:
Vibegron is a selective beta-3 adrenergic agonist. Like mirabegron, vibegron relaxes detrusor smooth muscle and increases bladder capacity, reducing incontinence.

Indication & Dosage:
For the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urinary urgency, and urinary frequency.
Oral dosage
- Adults: 75 mg PO once daily
- Adults & Geriatric Maximum Daily Dose: 75 mg/ day PO

Administration:
Administer with or without food. Swallow tablets whole with a glass of water. 75mg Tablets may be crushed and mixed with a tablespoonful (~15 mL) of applesauce. Swallow applesauce mixture immediately after preparation, followed by a glass of water.
No titration required.

Warnings/ Precautions/ Disease-related concerns:
- **Bladder flow obstruction:** Use with caution in patients with bladder outlet obstruction and in patients using concomitant muscarinic antagonists; may increase the risk of urinary retention. Monitor for signs and symptoms of urinary retention; discontinue use if urinary retention occurs.

Adverse Reactions:
Endocrine & metabolic: Hot flash (<2%),
Gastrointestinal: Constipation (<2%), diarrhea (2%), nausea (2%), xerostomia (<2%)
Genitourinary: Increased post-void residual urine volume (<2%), urinary retention (<2%),
Nervous system: Headache (4%),
Respiratory: Nasopharyngitis (3%), upper respiratory tract infection (2%)
Postmarketing: Dermatologic: Eczema, pruritus, skin rash

Special Populations:
- **Patients with Hepatic Impairment Dosing:**

Mild to moderate hepatic impairment (Child-Pugh A and B): No dosage adjustment is needed.
Severe hepatic impairment (Child-Pugh C):
Use is not recommended; vibegron has not been studied in this population.
- **Patients with Renal Impairment Dosing:**

eGFR 15 mL/minute/1.73 m2 or more: No dosage

Special Populations (continued):
adjustment is needed. eGFR 0 to 14 mL/minute/1.73 m2 (with or without hemodialysis): Use not recommended; vibegron has not been studied in this population.

Dosage Form/Storage:
Thirty (30) 75mg tablets in a 60 cc HDPE bottle with a child-resistant cap, **NDC 73336-075-30**
Ninety (90) tablets in a 60 cc HDPE bottle with a child-resistant cap, **NDC 73336-075-90**

Store at **20°C to 25°C (68°F to 77°F)**, excursions permitted to **15°C to 30°C (59°F to 86°F)**
[see USP Controlled Room Temperature]

Gemtesa® (Vibegron)

Efficacy and Safety of Vibegron for Treatment of OAB in Patients Aged ≥65 and ≥75 Years

DESIGN *12-Week, double-blind, randomized, placebo-controlled, and active-controlled trial in patients with OAB and symptons > 3*

INTERVENTIONS and ENDPOINTS

Randomized 5:5:4 to receive once-daily for 12 weeks, respectively:
- **Vibegron 75mg**
- **Placebo**
- **Tolterodine ER 4mg**

Co-primary endpoints:
- **Change in mean number of UUI episodes/day**
- **Change in mean number of micturitions/day**

RESULTS

Statistically significant improvements in # of incontinence episodes and micturition requency/day in vibegron group vs. placebo; rates were similar when compared with tolterodine group but better tolerability vs. tolterodine group

56 Varano S, et al. Drugs & Aging. 2021; 38:137–146

FOR COMPLETE PRESCRIBING INFORMATION:

medinfo@urovant.com • CALL: 1-833-UROVANT

Reference 66190 - Gemtesa (vibegron) tablets package insert. Irvine, CA: Urovant Sciences