### Living with overactive bladder (OAB)?

MORE

ERE

## LESS TIME THERE

## **GET TO KNOW GEMTESA**

#### WHAT IS GEMTESA?

GEMTESA is a prescription medicine used to treat the following symptoms due to a condition called overactive bladder (OAB) in adults, and in adult males taking medicine for benign prostatic hyperplasia (BPH): leakage episodes, urgency, and frequency.

It is not known if GEMTESA is safe and effective in children.

#### **IMPORTANT SAFETY INFORMATION**

**Do not** take GEMTESA if you are allergic to vibegron or any of the ingredients in GEMTESA.



## DON'T LET TRAVEL TAKE A BACK SEAT TO OAB

There are many misperceptions about OAB that may delay people like you from seeking treatment. Learn more about what to look for and find out how a treatment option may help with disruptive OAB symptoms.

## WHAT OAB IS

- Urge urinary incontinence (leakage episodes): when urine leaks from the bladder uncontrollably
- Urgency: a sudden and intense need to urinate even when the bladder is not full
- Frequency: the frequent urge to urinate (more than 8 times per day)

**†** 

#### **DID YOU KNOW?**

Urgency is the signature symptom of OAB.

#### WHAT OAB IS NOT

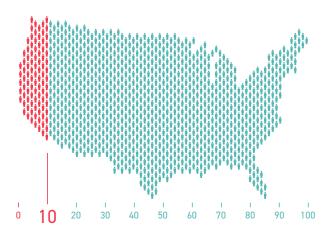
- Something you always have to cope with on your own
- A condition that always requires surgery for treatment
- 😢 Always treatable through lifestyle changes alone
- Something only women struggle with
- 🎸 Just a normal part of aging

#### **IMPORTANT SAFETY INFORMATION (CONT'D)**

Before you take GEMTESA, tell your doctor about all your medical conditions, including if you have liver problems; have kidney problems; have trouble emptying your bladder or you have a weak urine stream; take medicines that contain digoxin; are pregnant or plan to become pregnant (it is not known if GEMTESA will harm your unborn baby; talk to your doctor if you are pregnant or plan to become pregnant);

## OAB IS MORE COMMON THAN YOU THINK — YOU ARE NOT ALONE

Many people think OAB is a normal part of aging, but it doesn't have to be. You can do something about it.



Approximately 1 in 10 Americans are affected by bothersome OAB symptoms

### THAT'S ABOUT 33 MILLION PEOPLE.

And OAB symptoms in adults 65 and older are estimated to increase by 48% by 2027

#### **IMPORTANT SAFETY INFORMATION (CONT'D)**

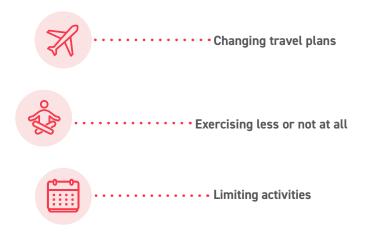
are breastfeeding or plan to breastfeed (it is not known if GEMTESA passes into your breast milk; talk to your doctor about the best way to feed your baby if you take GEMTESA).



## COPING IS COMMON WHEN LIVING WITH OAB SYMPTOMS

Ever find yourself cutting activities short to deal with your OAB symptoms? If so, you're not alone.

These are just a few ways people living with OAB may adjust their lifestyles to cope with their symptoms:



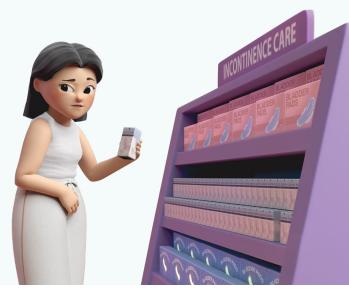
#### **DID YOU KNOW?**

In a survey of women diagnosed with OAB, many waited an average of 3 years after noticing symptoms to have a discussion with their doctor.

Why cope longer than you may have to? There's a treatment option that may help.

#### **IMPORTANT SAFETY INFORMATION (CONT'D)**

**Tell your doctor about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.



## These ways of coping may also be familiar to you:

- Wearing panty liners, pads, or absorbent briefs daily
- Packing extra underwear, pads, or clothes in case of an accident
- Mapping out the closest bathrooms when traveling or leaving home
- Carefully planning your commute

#### **IMPORTANT SAFETY INFORMATION (CONT'D)**

#### What are the possible side effects of GEMTESA?

GEMTESA may cause serious side effects including:

- inability to empty your bladder (urinary retention). GEMTESA may increase your chances of not being able to empty your bladder, especially if you have bladder outlet obstruction or take other medicines for treatment of overactive bladder. Tell your doctor right away if you are unable to empty your bladder.
- **angioedema.** GEMTESA may cause an allergic reaction with swelling of the lips, face, tongue, or throat, with or without difficulty breathing and may be life-threatening. Stop using GEMTESA and get emergency medical help right away if you have symptoms of angioedema or trouble breathing.



## DON'T SETTLE FOR JUST COPING — YOU'VE GOT OPTIONS

The sooner you talk with your doctor about your OAB symptoms, the sooner you can explore options or treatments that may help.



## Your doctor may suggest behavioral therapies, such as:

- Pelvic floor muscle training ("kegels")
- Creating a routine of scheduled bathroom trips
- Reducing fluid intake (especially at night) and avoiding food and drinks that may irritate your bladder (for example, alcohol and caffeine)

#### Your doctor may offer a medicine. There are 2 main types of prescription treatments available for treating OAB symptoms:

- Beta<sub>3</sub>-agonists (β<sub>3</sub>-agonists) work to lessen OAB symptoms by helping the bladder muscle relax so it can hold more urine
- Anticholinergics (AChs) work to lessen OAB symptoms by helping to stop involuntary bladder contractions (the bladder squeezing itself without your control)





#### Remember, everyone is unique

No treatment is right for everyone; you may need to try several treatments before finding the one that works for you. It's important to continue working with your doctor to find the best ways to manage your OAB symptoms.

#### **READY TO DO MORE THAN COPE?**

Use the questions on page 13 to help you start the discussion with your doctor to find out if GEMTESA is right for you.

### **IMPORTANT SAFETY INFORMATION (CONT'D)**

## What are the possible side effects of GEMTESA? (CONT'D)

The most common side effects of GEMTESA include headache, urinary tract infection, nasal congestion, sore throat or runny nose, diarrhea, nausea and upper respiratory tract infection. These are not all the possible side effects of GEMTESA. For more information, ask your doctor or pharmacist.

#### **IMPORTANT SAFETY INFORMATION (CONT'D)**

## What are the possible side effects of GEMTESA? (CONT'D)

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.



## GEMTESA MAY HELP YOU MOVE BEYOND JUST COPING



## **PROVEN RESULTS**

GEMTESA is proven to treat all 3 key OAB symptoms, including:

- Urge urinary incontinence: a strong need to urinate with leaking or wetting accidents
- Urgency: the need to urinate right away
- Frequency: urinating often

### A SIMPLE ROUTINE

- One single-dose pill taken once daily with or without food
- Swallow GEMTESA tablets 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 SIGNIFICANT IMPACT ON BLOOD PRESSURE

 In a clinical study, there were no clinically significant changes to hypertension or increased blood pressure vs placebo\*

\*In a clinical study of men and women, people taking GEMTESA and those taking placebo had similar rates of hypertension (1.7% [9 out of 545 people] vs 1.7% [9 out of 540 people], respectively) and increased blood pressure (0.7% [4 out of 545 people] vs 0.9% [5 out of 540 people], respectively). In a separate study of OAB in men being treated for BPH, rates of hypertension were 9.0% with GEMTESA (50 of 553 people) vs 8.3% with placebo (46 of 551 people).

#### **DID YOU KNOW?**

GEMTESA has been clinically proven to help reduce urgency episodes.

#### **IMPORTANT SAFETY INFORMATION**

**Do not** take GEMTESA if you are allergic to vibegron or any of the ingredients in GEMTESA.

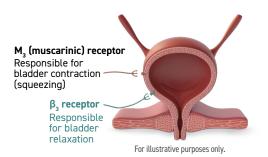
## GET TO KNOW OAB AND HOW GEMTESA WORKS

#### How your bladder works

As your bladder fills, nerve signals in your brain trigger your need to urinate. These signals tell your bladder to:

- Relax the muscles of the pelvic floor and urethra
- Contract (squeeze) the muscles in the bladder to release urine

However, when you're living with OAB, your bladder muscles may suddenly contract too frequently and too often, even when your bladder isn't full, creating an urgent feeling that you need to urinate.



#### How does GEMTESA help?

GEMTESA is a type of medication called a "beta<sub>3</sub>agonist," which is designed to help relax your bladder muscle so it can hold more urine. This may help to reduce the urgent need to run to the bathroom and the number of times you experience leakage.



## SIGNIFICANT IMPROVEMENT IN OAB SYMPTOM RELIEF AT 12 WEEKS

In a 12-week clinical study:



People taking GEMTESA had 2 fewer daily leakage episodes compared with about 1 (-1.4) fewer episode for those taking placebo\*



People taking GEMTESA had nearly 2 (-1.8) fewer bathroom visits per day compared with about 1 (-1.3) fewer visit per day for those taking placebo<sup>†</sup>



People taking GEMTESA had nearly 3 (-2.7) fewer bathroom visits with "urge to go" feelings compared with 2 fewer visits for those taking placebo<sup>†</sup>

The efficacy and safety of GEMTESA was studied in a 12-week trial of people with symptoms of OAB (urge urinary incontinence, urgency, frequency).

\*403 people received GEMTESA and 405 people received placebo. †526 people received GEMTESA and 520 people received placebo.

#### **IMPORTANT SAFETY INFORMATION (CONT'D)**

Before you take GEMTESA, tell your doctor about all your medical conditions, including if you have liver problems; have kidney problems; have trouble emptying your bladder or you have a weak urine stream; take medicines that contain digoxin; are pregnant or plan to become pregnant (it is not known if GEMTESA will harm your unborn baby; talk to your doctor if you are pregnant or plan to become pregnant); are breastfeeding or plan to breastfeed (it is not known if GEMTESA passes into your breast milk; talk to your doctor about the best way to feed your baby if you take GEMTESA). Additional clinical study results seen at 12 weeks:



About half (52%) of people taking GEMTESA saw a 75% or greater reduction in daily leakage episodes vs 37% for people taking placebo\*‡



#### BE SURE TO TALK TO YOUR DOCTOR ABOUT WHETHER GEMTESA IS RIGHT FOR YOU

<sup>‡</sup>The information was derived from the observed data for a predetermined secondary study outcome.

#### **IMPORTANT SAFETY INFORMATION (CONT'D)**

**Tell your doctor about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.



## **ESTABLISHED SAFETY IN A CLINICAL STUDY AT 12 WEEKS**

The most common side effects of GEMTESA in a clinical trial were headache, urinary tract infection, nasal congestion, sore throat or runny nose, diarrhea, nausea, and upper respiratory tract infection

#### **GEMTESA** had no significant impact on blood pressure.

- In a 12-week study of men and women, people taking GEMTESA and those taking placebo had similar rates of hypertension (1.7% [9 out of 545 people] vs 1.7% [9 out of 540 people], respectively) and increased blood pressure (0.7% [4 out of 545 people] vs 0.9% [5 out of 540 people], respectively)
- In a separate 24-week clinical study of men with OAB symptoms being treated for BPH,

hypertension occurred in those taking GEMTESA (9.0% [50 out of 553 people]) and those taking placebo (8.3% [46 out of 551 people])



## **IMPORTANT SAFETY INFORMATION (CONT'D)**

Less than 2% of people stopped taking GEMTESA because of side effects

#### What are the possible side effects of GEMTESA?

GEMTESA may cause serious side effects including:

- inability to empty your bladder (urinary retention). GEMTESA may increase your chances of not being able to empty your bladder, especially if you have bladder outlet obstruction or take other medicines for treatment of overactive bladder. Tell your doctor right away if you are unable to empty your bladder.
- angioedema. GEMTESA may cause an allergic reaction with swelling of the lips, face, tongue, or throat, with or without difficulty breathing and may be life-threatening. Stop using GEMTESA and get emergency medical help right away if you have symptoms of angioedema or trouble breathing.

## **GETTING THE HELP YOU NEED**

If you've decided that it's time to take the next step, use these questions to start a discussion with your doctor to find out if GEMTESA is right for you:





How often do I need to take GEMTESA?

Is GEMTESA proven

to reduce urgency?

What side effects can I expect?

When may I begin to see results after starting GEMTESA?

#### See how real people taking GEMTESA went from just coping to managing OAB:



Visit TimeToGo.com

#### **IMPORTANT SAFETY INFORMATION (CONT'D)**

#### What are the possible side effects of GEMTESA? (CONT'D)

The most common side effects of GEMTESA include headache, urinary tract infection, nasal congestion, sore throat or runny nose, diarrhea, nausea and upper respiratory tract infection. These are not all the possible side effects of GEMTESA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.



## STILL WONDERING IF GEMTESA IS RIGHT FOR YOU?



#### Discover even more about OAB and GEMTESA

Visit <u>GEMTESA.com</u> for tools and resources, such as:

**Emails and text reminders** 

An OAB Self-assessment Quiz

Tips, motivation, and so much more



#### **IMPORTANT SAFETY INFORMATION**

**Do not** take GEMTESA if you are allergic to vibegron or any of the ingredients in GEMTESA.

**Before you take GEMTESA, tell your doctor about all your medical conditions, including if you** have liver problems; have kidney problems; have trouble emptying your bladder or you

## READY TO GET GOING WITH GEMTESA? - - - -



If you've already received a prescription or sample of GEMTESA from your doctor

Visit <u>StartGEMTESA.com</u> to make the most of your treatment journey. You'll find more on:

What to expect as you begin treatment

Costs & coverage options for you

**Real GEMTESA experiences from others** 

Useful tools and support offerings

VISIT <u>StartGEMTESA.com</u> FOR THESE HELPFUL RESOURCES AND MORE TO HELP NAVIGATE YOUR OAB TREATMENT

#### **IMPORTANT SAFETY INFORMATION (CONT'D)**

have a weak urine stream; take medicines that contain digoxin; are pregnant or plan to become pregnant (it is not known if GEMTESA will harm your unborn baby; talk to your doctor if you are pregnant or plan to become pregnant); are breastfeeding or plan to breastfeed (it is not known if GEMTESA passes into your breast milk; talk to your doctor about the best way to feed your baby if you take GEMTESA).



## IMPORTANT PRODUCT INFORMATION

#### What is GEMTESA?

GEMTESA is a prescription medicine used to treat the following symptoms due to a condition called overactive bladder (OAB) in adults, and in adult males taking medicine for benign prostatic hyperplasia (BPH): leakage episodes, urgency, and frequency. It is not known if GEMTESA is safe and effective in children.

#### **IMPORTANT SAFETY INFORMATION**

**Do not** take GEMTESA if you are allergic to vibegron or any of the ingredients in GEMTESA.

Before you take GEMTESA, tell your doctor about all your medical conditions, including if you have liver problems; have kidney problems; have trouble emptying your bladder or you have a weak urine stream; take medicines that contain digoxin; are pregnant or plan to become pregnant (it is not known if GEMTESA will harm your unborn baby; talk to your doctor if you are pregnant or plan to become pregnant); are breastfeeding or plan to breastfeed (it is not known if GEMTESA passes into your breast milk; talk to your doctor about the best way to feed your baby if you take GEMTESA).

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

#### What are the possible side effects of GEMTESA?

GEMTESA may cause serious side effects including:

- inability to empty your bladder (urinary retention). GEMTESA may increase your chances of not being able to empty your bladder, especially if you have bladder outlet obstruction or take other medicines for treatment of overactive bladder. Tell your doctor right away if you are unable to empty your bladder.
- **angioedema.** GEMTESA may cause an allergic reaction with swelling of the lips, face, tongue, or throat, with or without difficulty breathing and may be life-threatening. Stop using GEMTESA and get emergency medical help right away if you have symptoms of angioedema or trouble breathing.

The most common side effects of GEMTESA include headache, urinary tract infection, nasal congestion, sore throat or runny nose, diarrhea, nausea and upper respiratory tract infection. These are not all the possible side effects of GEMTESA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see Patient Information about GEMTESA here.

## MAKE NOTE OF PERSONAL GOALS

Use the space below to jot down your symptoms, treatment goals, questions for your doctor, and notes from your visit.

Symptoms I've noticed: My treatment goals: **Questions for my doctor:** Notes from my doctor's visit:



#### FOR COMMERCIALLY INSURED PATIENTS, YOU MAY PAY AS LITTLE AS



#### YOU MAY PAY AS LITTLE AS \$10 FOR EVERY 30-DAY SUPPLY\*

If you have commercial insurance (government plans like Medicare or Medicaid are not eligible) and GEMTESA is not covered by your plan, **you may pay as little as \$95\* for every 30-day supply.** 

SEE IF YOU ARE ELIGIBLE NOW THROUGH DECEMBER 31, 2025.

For questions about this program, please call: 1-833-876-8268.

\*Restrictions and maximum saving limits apply. Coverage and out-of-pocket costs may vary. **Offer not** valid for patients participating in Medicare, Medicaid, or other government healthcare programs. See full program terms, conditions, and eligibility criteria at <u>GEMTESA.com/card</u>.

#### Sign up today using your preferred method:



Text "**GEMTESA**" to **436872** 



Visit GEMTESA.com/card

Message and data rates may apply. Up to 15 messages per month after initial sign-up communications. Text STOP to unsubscribe at any time.

Please see inside for Important Safety Information and Patient Information about GEMTESA <u>here</u>.

#### Sumitomo Pharma

◆ is a trademark of Sumitomo Pharma Co., Ltd., used under license. SUMITOMO PHARMA is a trademark of Sumitomo Pharma Co., Ltd., used under license. SUMITOMO is a registered trademark of Sumitomo Chemical Co., Ltd., used under license. Sumitomo Pharma America, Inc. is a U.S. subsidiary of Sumitomo Pharma Co., Ltd.

GEMTESA, and the GEMTESA logo are trademarks of Urovant Sciences GmbH, registered in the U.S. and in other countries. ©2025 Sumitomo Pharma America, Inc. All rights reserved. GEM-US-2524-24 03/25





#### **IMPORTANT INFORMATION**

This is a summary of information about GEMTESA. This does not take the place of talking with your doctor about your medical condition or treatment.

#### What is **GEMTESA**?

GEMTESA is a prescription medicine that can be used to treat the following symptoms of overactive bladder in adults, and in adult males taking medicine for benign prostatic hyperplasia (BPH):

- **urge urinary incontinence:** a strong need to urinate with leaking or wetting accidents
- **urgency:** the need to urinate right away
- frequency: urinating often

It is not known if GEMTESA is safe and effective in children.

Who should not take GEMTESA?

- **Do not** take GEMTESA if you are allergic to vibegron or any of the ingredients in GEMTESA
  - Active ingredient: vibegron
  - Inactive ingredients: croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, mannitol, and microcrystalline cellulose. The light green film coating contains FD&C Blue No. 2 - aluminum lake, hypromellose, iron oxide yellow, lactose monohydrate, titanium dioxide, and triacetin

## What should I tell my doctor before taking GEMTESA?

Before you take GEMTESA, tell your doctor about all of your medical conditions, including if you:

- have liver problems
- have kidney problems
- have trouble emptying your bladder or you have a weak urine stream
- take medicines that contain digoxin
- are pregnant or plan to become pregnant. It is not known if GEMTESA will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed. It is not known if GEMTESA passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take GEMTESA

# a

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

## What are the possible side effects of GEMTESA?

GEMTESA may cause serious side effects, including:

- inability to empty your bladder (urinary retention). GEMTESA may increase your chances of not being able to empty your bladder, especially if you have bladder outlet obstruction or take other medicines for treatment of overactive bladder. Tell your doctor right away if you are unable to empty your bladder
- **angioedema.** GEMTESA may cause an allergic reaction with swelling of the lips, face, tongue, or throat, with or without difficulty breathing and may be life-threatening. Stop using GEMTESA and get emergency medical help right away if you have symptoms of angioedema or trouble breathing

#### The most common side effects of GEMTESA include:

- headache
- urinary tract infection
- nasal congestion, sore throat or runny nose
- diarrhea
- nausea
- upper respiratory tract infection



These are not all the possible side effects of GEMTESA. For more information, ask your doctor or pharmacist. **Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.** 

## Is there any other important information I should know?

- This is only a summary of the important information about GEMTESA. To learn more, talk with your healthcare provider or pharmacist
- The FDA-approved product labeling can be found at GEMTESA.com
- You may also report side effects to the FDA at 1-800-FDA-1088

◆ is a trademark of Sumitomo Pharma Co., Ltd., used under license. SUMITOMO PHARMA is a trademark of Sumitomo Pharma Co., Ltd., used under license. SUMITOMO is a registered trademark of Sumitomo Chemical Co., Ltd., used under license. Sumitomo Pharma America, Inc. is a U.S. subsidiary of Sumitomo Pharma Co., Ltd.

GEMTESA, and the GEMTESA logo are trademarks of Urovant Sciences GmbH, registered in the U.S. and in other countries.

©2025 Sumitomo Pharma America, Inc. GEM-US-2545-24 01/25

### Sumitomo Pharma