

Get Set Tracker

Helping you set personal treatment goals and stay on track

GEMTESA[®]
(vibegron) 75 mg tablets

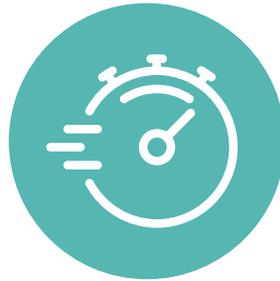
THE NEXT STEP STARTS HERE

You're on a roll now! This personal tracker will help you get set to track your symptom changes while taking GEMTESA.

Inside you'll find:



LIFESTYLE TIPS



GOAL-SETTING ACTIVITIES



TRACKER SHEETS

BE SURE TO KEEP YOUR TRACKER HANDY DURING THE DAY SO YOU CAN TRACK IN REAL TIME

TIPS AND TRICKS TO STAY ON TRACK

Talk to your doctor about adding some of the lifestyle changes below into your daily routine to help manage symptoms while taking GEMTESA:



HYDRATION

It's important to stay hydrated, so try not to limit your fluid intake.



IRRITANTS

You can help reduce your urge to go by avoiding common bladder irritants like caffeinated or carbonated drinks, citrus juices, and spicy foods.



PHYSICAL ACTIVITY

Staying physically active is generally good for you—but the great thing about pelvic floor exercises, or Kegel exercises, is that they can actually help decrease leakage episodes.

NOW, SET YOUR TREATMENT GOAL

Staying on track with your treatment is all about setting goals that work for you because everyone is unique. When you're focused on the changes you'd personally like to see, you'll know whether treatment is working for you.

What am I hoping to change or improve with treatment?

In one month my goal is to:

DON'T FORGET TO LOOK BACK AT THESE GOALS TO CHECK ON YOUR PROGRESS

GEMTESA is a prescription medication for the treatment of overactive bladder (OAB) in adults with symptoms of urgency, frequency and leakage episodes.

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

Please see Important Safety Information on page 4.

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STEP 1

STEP 1: TRACKING YOUR BASELINE FOR DAY 1

Fill in the chart below immediately after starting treatment.

TRIPS TO THE BATHROOM	6AM – 6PM	6PM – 6AM
How many times?		
Was urination urgent? (Circle one)	YES NO	YES NO
How urgent? (5 = most urgent)	1 2 3 4 5	1 2 3 4 5
What was I doing right before needing to go to the bathroom?		

LEAKAGE EPISODES	6AM – 6PM	6PM – 6AM
How many times?		
Number of bathroom trips with leakage?		
Average amount of leakage (Circle one: Small, Medium, or Large)	S M L	S M L
Number of bathroom trips without leakage?		

What did I drink/eat before leakage episode?

DRINKS	6AM – 6PM	6PM – 6AM
Any bladder-irritating drinks? (Circle one)	YES NO	YES NO
What kind?		
How much?		

FOOD	6AM – 6PM	6PM – 6AM
Any bladder-irritating food? (Circle one)	YES NO	YES NO
What kind?		
How much?		

PAD USAGE	6AM – 6PM	6PM – 6AM
How many?		

Were any activities interrupted today due to my OAB symptoms?
YES | NO
If so, describe:

TRACKING YOUR BASELINE

Start by filling out tracker sheets for 2 days to record your normal bladder activity immediately after starting treatment with GEMTESA.

STEP 1: TRACKING YOUR BASELINE FOR DAY 2

Fill in the chart below immediately after starting treatment.

TRIPS TO THE BATHROOM	6AM – 6PM	6PM – 6AM
How many times?		
Was urination urgent? (Circle one)	YES NO	YES NO
How urgent? (5 = most urgent)	1 2 3 4 5	1 2 3 4 5
What was I doing right before needing to go to the bathroom?		

LEAKAGE EPISODES	6AM – 6PM	6PM – 6AM
How many times?		
Number of bathroom trips with leakage?		
Average amount of leakage (Circle one: Small, Medium, or Large)	S M L	S M L
Number of bathroom trips without leakage?		

What did I drink/eat before leakage episode?

DRINKS	6AM – 6PM	6PM – 6AM
Any bladder-irritating drinks? (Circle one)	YES NO	YES NO
What kind?		
How much?		

FOOD	6AM – 6PM	6PM – 6AM
Any bladder-irritating food? (Circle one)	YES NO	YES NO
What kind?		
How much?		

PAD USAGE	6AM – 6PM	6PM – 6AM
How many?		

Were any activities interrupted today due to my OAB symptoms?
YES | NO
If so, describe:

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STEP 2

STEP 2: TRACKING YOUR PROGRESS WITH GEMTESA

Fill in the chart below within a few days of your next OAB specialist appointment.

TRIPS TO THE BATHROOM	6AM - 6PM	6PM - 6AM
How many times?		
Was urination urgent? (Circle one)	YES NO	YES NO
How urgent? (5 = most urgent)	1 2 3 4 5	1 2 3 4 5
What was I doing right before needing to go to the bathroom?		

LEAKAGE EPISODES	6AM - 6PM	6PM - 6AM
How many times?		
Number of bathroom trips with leakage?		
Average amount of leakage (Circle one: Small, Medium, or Large)	S M L	S M L
Number of bathroom trips without leakage?		

SYMPTOMS	6AM - 6PM	6PM - 6AM
Experiencing less symptoms since last entry?		

What did I drink/eat before leakage episode?

DRINKS	6AM - 6PM	6PM - 6AM
Any bladder-irritating drinks? (Circle one)	YES NO	YES NO
What kind?		
How much?		

FOOD	6AM - 6PM	6PM - 6AM
Any bladder-irritating food? (Circle one)	YES NO	YES NO
What kind?		
How much?		

PAD USAGE	6AM - 6PM	6PM - 6AM
How many?		

Were any activities interrupted today due to my OAB symptoms?
 YES | NO
 If so, describe:

TRACKING PROGRESS WITH GEMTESA

Before your follow-up appointment, be sure to fill out 2 more days of tracker sheets and compare to your baseline bladder activity.

STEP 2: TRACKING YOUR PROGRESS WITH GEMTESA

Fill in the chart below within a few days of your next OAB specialist appointment.

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PAD USAGE	6AM - 6PM	6PM - 6AM
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STEP 3

SHARE WITH YOUR OAB SPECIALIST

Grab your tracker before your next appointment to share how you are doing.

STEP 3: SHARING WITH YOUR OAB SPECIALIST IS KEY

You made it! Now, it's time to share your tracker results with your OAB specialist.

INDICATION & IMPORTANT SAFETY INFORMATION

What is GEMTESA?

GEMTESA is a prescription medicine for adults used to treat the following symptoms due to a condition called overactive bladder:

- 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.

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 **the 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.

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 full Prescribing Information at www.GEMTESA.com/PI.

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PATIENT INFORMATION
GEMTESA [gem tes' ah]
(vibegron)
tablets, for oral use

What is GEMTESA?

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- 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.

Do not take GEMTESA if you:

- are allergic to vibegron or any of the ingredients in GEMTESA. See the end of this leaflet for a complete list of ingredients in 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.

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.

How should I take GEMTESA?

- Take GEMTESA exactly as your doctor tells you to take it.
- Take 1 GEMTESA tablet, by mouth, 1 time a day with or without food.
- Swallow GEMTESA tablets whole with a glass of water.
- You may also crush GEMTESA tablets, mix with 1 tablespoon (about 15 mL) of applesauce, and take right away with a glass of water.

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.

The most common side effects of GEMTESA include:

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

How should I store GEMTESA?

- Store GEMTESA at room temperature between 68°F to 77°F (20°C to 25°C).
- Safely throw away medicine that is no longer needed in your household trash.
- You may also dispose of the unused medicine through a take-back option, if available. See www.fda.gov/drugdisposal for more information.

Keep GEMTESA and all medicines out of the reach of children.

General information about the safe and effective use of GEMTESA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use GEMTESA for a condition for which it was not prescribed. Do not give GEMTESA to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your doctor or pharmacist for information about GEMTESA that is written for health professionals.

What are 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.

Manufactured for and Distributed by:

Sumitomo Pharma America, Inc.

Marlborough, MA 01752



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For more information, go to www.GEMTESA.com or call 1-833-876-8268.



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This Patient Information has been approved by the U.S. Food and Drug Administration.

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