

Let's Go Tracker

Helping you set personal treatment goals and stay on track



Moving Forward With GEMTESA

Congrats on starting treatment with GEMTESA!
This guide is here to help you navigate your next steps – your way.

This tracker includes:



Lifestyle Tips



Goal Setting Activities



Tracker Sheets



Questions to Ask Your Doctor

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:



Stay hydrated

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



Avoid Irritants

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



Be active

Staying physically active is generally good for you – but the great thing about pelvic floor exercises, or Kegels, is that they may help decrease leakage episodes.

What is GEMTESA?

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

IMPORTANT SAFETY INFORMATION

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

Please see Important Safety Information on pages 5 and 6 and Patient Information [here](#).

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.

Things I'm excited to do once I start treatment:

Check in with your goals at your follow-up appointment as well!

Let's Go Tracker

Helping you set personal treatment goals and stay on track



STEP 1

Track your baseline

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

Day 1

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 did I rush to the bathroom because of 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:

Day 2

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 did I rush to the bathroom because of 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:

Let's Go Tracker

Helping you set personal treatment goals and stay on track

STEP 2

Track 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.

2 days before check in:

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 did I rush to the bathroom because of 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?	YES NO	YES NO

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:

1 day before check in:

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 did I rush to the bathroom because of 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?	YES NO	YES NO

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:

Let's Go Tracker

Helping you set personal treatment goals and stay on track



Share with your OAB specialist

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

Use the area below to jot down any notes or questions you have.

A large rectangular area enclosed by a dashed teal border, containing 20 horizontal teal lines for writing notes or questions.

Now What?

A guide to help you ask the right questions about GEMTESA



There's more to your world than just coping with OAB. Finding a treatment plan that works for you takes teamwork with your treatment provider. Think of your follow-up appointment as **you** time — it's the time to talk about your questions and care, and let your doctor know how your treatment is going with the Let's Go Tracker.

Remember: symptom improvement doesn't happen overnight. You have to be consistent in your treatment plan to see continued results!

OAB Check In

This tool is a great way to see how far you've come on your treatment journey in 5 easy questions. If you've used the tool before, you can compare your new answers to your previous results. If not, no worries! Share these results as well as your tracker with your OAB treatment provider and make sure to ask any questions you may have — you can find some below to help get the conversation started!

How many times do you urinate during the day? (Frequency)

- 1-7 times 8-12 times 13 or more

How often do you leak after feeling a strong urge to go? (Urge urinary incontinence)

- Not at all Several times a day
 About once per day Almost always

How much do these symptoms bother you?

- Not at all
 Annoying but bearable
 I need relief now

How often do you have a strong, sudden urge to urinate that makes you feel like you will leak if you don't get to a bathroom immediately? (Urgency)

- Not at all Several times a day
 About once per day Almost always

Have you canceled trips, avoided exercising, or refused invitations because you weren't sure you'd be close to a bathroom?

- Never
 Once or twice
 All the time

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.

Please see continued Important Safety Information on page 6.

Now What?

A guide to help you ask the right questions about GEMTESA



Questions to ask your doctor at your follow-up appointment

- I've been taking this for some time now. How much longer should I stick with my treatment plan?
- How exactly does GEMTESA help?
- Should I make any changes to my lifestyle?
- It's been some time now and I've noticed a difference in my symptoms. Will I continue to see symptom improvement? What about frequency, leakage, and my strong urge to go?
- I know that OAB is a chronic condition. Can you tell me why that means I need to continue taking GEMTESA daily?

Indication & Important Safety Information (cont'd)

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.



◆ 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. ©2024 Sumitomo Pharma America, Inc. All rights reserved. US-VBGN-2400010 03/24

PATIENT INFORMATION

GEMTESA [gem tes' ah]

(vibegron)

tablets, for oral use

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.

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

 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.
All other trademarks are the property of their respective owners.

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



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

Approved: 07/2023
US-VBGN-2000168 (v3.0)