



GATTEX® (teduglutide [rDNA origin]) for Injection is a prescription medicine used in adults with Short Bowel Syndrome (SBS) who need additional nutrition or fluids from intravenous (IV) feeding (parenteral support).



GETTING STARTED WITH GATTEX®

IMPORTANT SAFETY INFORMATION: GATTEX may cause serious side effects including making abnormal cells grow faster, polyps in the colon (large intestine), blockage of the bowel (intestines), swelling (inflammation) or blockage of your gallbladder or pancreas, and fluid overload.

Please see **Important Safety Information** on pages 7 and 8, click for full [Prescribing Information](#) and [Medication Guide](#), and discuss any questions with your doctor.



When you're getting started on GATTEX, it helps to have an experienced partner guide you through the process.

That's why OnePath[®] provides you with a dedicated Patient Support Manager and Onboarding and Access Specialist who work with you one on one. Your OnePath team will help you gain access to your medication and provide resources related to your condition throughout your treatment journey.

Your Onboarding and Access Specialist will work with you and certain members of your healthcare team when you're beginning therapy. He or she will personally meet with you to guide you through the process of getting started with your GATTEX treatment, provide a resource kit with educational materials and answer questions you have about access to your treatment. Your Patient Support Manager will continue working with you to provide product support on an ongoing basis.

You can count on your Patient Support Manager and/or Onboarding and Access Specialist to help tackle lots of important tasks, like these:

- ✓ **Navigating your insurance**
What's covered? What's not? We'll provide answers and give you options.
- ✓ **Getting your prescription filled**
We can work with your specialty pharmacy to make sure your medicine is delivered.
- ✓ **Discussing finances**
We'll provide information about financial assistance options.
- ✓ **Arranging training from a nurse educator**
If you and your doctor decide you should schedule injection training, let us know and we'll arrange it. You must have a conversation with your Nurse Educator before they can visit your home.

Your OnePath team is here every step of the way

Your Patient Support Manager will contact you to:

- Verify your insurance coverage information
- Connect you with your OnePath Onboarding and Access Specialist, Specialty Pharmacist and Nurse Educator

Your Onboarding and Access Specialist will:

- Work closely with you during the first few months
- Provide educational information about GATTEX for you to discuss with your doctor
- Provide information about potential options for financial assistance, if needed
- Answer any questions you may have about the steps to getting GATTEX as prescribed

Please see Important Safety Information on pages 7 and 8, click for full [Prescribing Information](#) and [Medication Guide](#), and discuss any questions with your doctor.



Your Patient Support Manager and Onboarding and Access Specialist work together with you to arrange for your specialty pharmacy to ship your medication. You should know that you must have a phone conversation with your specialty pharmacy before your medication can be shipped.

Once you receive your medication, your Patient Support Manager can also coordinate injection training from a registered nurse.

DID YOU KNOW?

Specialty pharmacies provide a variety of specialized services which may include selling and providing timely delivery of specialty pharmaceuticals and supplies, working with patients and their healthcare providers to implement the prescribed care plan, and helping manage reimbursement issues; also referred to as a specialty pharmacy provider (SPP).



You will receive a phone call from a nurse to set up your injection training.

- The nurse will come to your home to teach you how to prepare, measure your dose, and give your injection of GATTEX the right way.
- If someone will be helping you with your injections, such as a caregiver, family member or friend, then you should ask this person to attend the training with you. That way, they'll also know how to administer your GATTEX injection the right way.
- The nurse will review information about GATTEX with you, including an important document that's been approved by the U.S. Food and Drug Administration (FDA). This document is called the [Instructions for Use](#). Be sure to read this document before you start using GATTEX and each time you receive a refill since there may be new information.
- Please remember that this nurse home visit does not take the place of talking with your doctor about your treatment plan.
- If you have questions after you've completed your training, don't worry. You can reach a nurse who can answer questions regarding GATTEX. Just call OnePath (1-866-888-0660) and follow prompts to speak to a nurse about mixing, administering and storing GATTEX. OnePath is open Monday through Friday, 8:30 a.m. to 8:00 p.m. EST.

How should I use GATTEX?

- Use GATTEX exactly as your healthcare provider tells you to.
- GATTEX is given 1 time each day at the same time.
- Inject your dose of GATTEX under the skin (subcutaneous injection) in your stomach area (abdomen), upper legs (thighs), or upper arms. **Do not inject GATTEX into a vein or muscle.**
- Use a different injection site each time you use GATTEX.
- GATTEX comes as a powder for injection in a vial that is used only 1 time (single-use vial). The powder must be mixed with Sterile Water for Injection (a diluent) provided in a pre-filled syringe before you inject it.
- GATTEX must be injected within 3 hours after you mix it with the diluent.
- **If you miss a dose, take it as soon as you remember that day. Take your next dose the next day at the same time you take it every day.**
- **Do not take 2 doses on the same day.**
- **If you use more than 1 dose, call your healthcare provider right away.**
- Read the [Instructions for Use](#) for detailed instructions for preparing and injecting a dose of GATTEX.

DID YOU KNOW?

Your healthcare provider or nurse should show you how to prepare, measure your dose, and give your injection of GATTEX the right way. You can also visit the GATTEX website to watch a video on instructions for use.

Go to: www.gattex.com/start-gattex/how-to-use-gattex

How should I store GATTEX?

- Store GATTEX powder at room temperature up to 25°C (77°F).
- Do not freeze GATTEX.
- Use the GATTEX powder by the expiration date on the “Use By” sticker on the kit. Use GATTEX within 3 hours after mixing it.
- Throw away any unused GATTEX that has been mixed, even if there is medicine left in the vial.
- Do not store any GATTEX you have mixed.



Please see Important Safety Information on pages 7 and 8, click for full [Prescribing Information](#) and [Medication Guide](#), and discuss any questions with your doctor.

Important Safety Information

What is the most important information I should know about GATTEX® (teduglutide [rDNA origin]) for Injection?

GATTEX may cause serious side effects, including:

Making abnormal cells grow faster

GATTEX can make abnormal cells that are already in your body grow faster. There is an increased risk that abnormal cells could become cancer. If you get cancer of the bowel (intestines), liver, gallbladder or pancreas while using GATTEX, your healthcare provider should stop GATTEX. If you get other types of cancers, you and your healthcare provider should discuss the risks and benefits of using GATTEX.

Polyps in the colon (large intestine)

Polyps are growths on the inside of the colon. Polyps were found in patients taking GATTEX in clinical studies. Your healthcare provider will have your colon checked for polyps within 6 months before starting GATTEX and have any polyps removed.

To keep using GATTEX, your healthcare provider should have your colon checked for new polyps at the end of 1 year of using GATTEX. If no polyp is found, your healthcare provider should check you for polyps as needed and at least every 5 years and have any new polyps removed. If cancer is found in a polyp, your healthcare provider should stop GATTEX.

Blockage of the bowel (intestines)

A bowel blockage keeps food, fluids, and gas from moving through the bowels in the normal way. Bowel blockage was reported in patients taking GATTEX in clinical studies. Tell your healthcare provider if you have any of these symptoms of a bowel blockage:

- trouble having a bowel movement or passing gas
- stomach area (abdomen) pain or swelling
- nausea
- vomiting
- swelling and blockage of your stoma opening, if you have a stoma

If blockage is found, your healthcare provider may temporarily stop GATTEX.

Swelling (inflammation) or blockage of your gallbladder or pancreas

Swelling or blockage of the gallbladder or pancreas were reported in patients taking GATTEX in clinical studies. Your healthcare provider will do tests to check your gallbladder and pancreas within 6 months before starting GATTEX and at least every 6 months while you are using GATTEX. Tell your healthcare provider right away if you get stomach area (abdomen) pain and tenderness, chills, fever, change in your stools, nausea, vomiting, dark urine, or yellowing of your skin or the whites of eyes.

Fluid overload

Fluid overload and heart failure were reported in patients taking GATTEX in clinical studies. Too much fluid in your body may lead to heart failure, especially if you have heart problems. Your healthcare provider will check you for too much fluid in your body. Tell your healthcare provider if you get swelling in your feet and ankles, you gain weight very quickly (water weight), or you have trouble breathing.

Important Safety Information (continued)

The most common side effects of GATTEX® (teduglutide [rDNA origin]) for Injection include:

- stomach area (abdomen) pain or swelling
- skin reaction where the injection was given
- nausea
- headache
- cold or flulike symptoms
- vomiting

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

What should I tell my healthcare provider before using GATTEX?

Tell your healthcare provider if you:

- have cancer or a history of cancer
- have or had polyps anywhere in your bowel (intestines) or rectum
- have heart problems
- have high blood pressure
- have problems with your gallbladder, pancreas, kidneys
- have any other medical condition
- are pregnant or planning to become pregnant. It is not known if GATTEX will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while using GATTEX.
- are breastfeeding or plan to breastfeed. It is not known if GATTEX passes into your breast milk. You and your healthcare provider should decide if you will use GATTEX or breastfeed. You should not do both.

Tell your healthcare providers about all the medicines you take, including prescription or over-the-counter medicines, vitamins, and herbal supplements. Using GATTEX with certain other medicines may affect each other causing side effects. Your other healthcare providers may need to change the dose of any oral medicines you take while using GATTEX. Tell the healthcare provider who gives you GATTEX if you will be taking a new oral medicine.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For additional safety information, click for full [Prescribing Information](#) and [Medication Guide](#), and discuss any questions with your doctor.

Gattex[®]
(Teduglutide [rDNA origin]) for Injection



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Please see additional Important Safety Information on pages 7 and 8, and click here for the full [Prescribing Information](#) and [Medication Guide](#) and discuss any questions with your doctor.