



FREQUENTLY ASKED QUESTIONS ABOUT GATTEX

An educational guide for people living with
short bowel syndrome (SBS) & their caregivers

What is GATTEX?

GATTEX® (teduglutide) for subcutaneous injection is a prescription medicine used in adults and children 1 year of age and older with Short Bowel Syndrome (SBS) who need additional nutrition or fluids from intravenous (IV) feeding (parenteral support). It is not known if GATTEX is safe and effective in children under 1 year of age.

What is the most important information I should know about GATTEX?

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 18-19, click for full [Prescribing Information and Medication Guide](#), and discuss any questions with your doctor.

**Gattex**[®]
(teduglutide) for injection



YOUR GATTEX QUESTIONS ANSWERED

When taking GATTEX, it's important for you to be as informed as possible and maintain an open dialogue with your healthcare team. Since everyone can have a different experience with GATTEX, we wanted to provide you with answers to some of the most frequently asked questions.

Here are the topics we cover



About GATTEX



How to store GATTEX



Possible side effects with GATTEX



Support and resources



How to use GATTEX



For parents and caregivers of children on GATTEX

We hope these answers help. If you don't see what you're looking for, we encourage you to talk to your doctor or Onboarding and Access Specialist (OAS) contact.

Remember, this information is not designed to replace discussions with your doctor. Always consult your doctor if you have any issues or concerns with your medication.



You can also call OnePath at 1-866-888-0660, Mon-Fri, 8 AM-8 PM ET. OnePath provides a range of product support services throughout your GATTEX treatment journey.



KAT,
GATTEX PATIENT

Please see Important Safety Information on pages 18-19, click for full [Prescribing Information and Medication Guide](#), and discuss any questions with your doctor.





ABOUT GATTEX

What is GATTEX?

GATTEX (teduglutide) is a prescription medicine used in adults and children 1 year of age and older with Short Bowel Syndrome (SBS) who need additional nutrition or fluids from intravenous (IV) feeding (parenteral support).

How does GATTEX work?

GLP-2, short for glucagon-like peptide-2, is a natural hormone produced in the intestine that helps the body absorb nutrients and fluids. GATTEX works like the GLP-2 that your body normally makes on its own.

How does GLP-2 impact the way the body absorbs nutrients?

Usually, people with SBS have undergone surgery to remove parts of the intestine. This may include portions that produce GLP-2. Without enough GLP-2, the nutrients and fluids your body absorbs from the things you eat and drink can be limited.

How long does it take for GATTEX to start working?

Not everyone responds to GATTEX the same way, and your body may need time to adjust. Therefore, it may take time to work. It's important to be patient and follow your doctor's guidance. In clinical studies, some adults were able to reduce weekly PS volume after about 1 month of treatment. For others, it took 12 months or longer. And some did not respond at all. For the majority of children, GATTEX started to work within 6 months. For some children, it may take longer, or they may not respond at all.

Can GATTEX help reduce dependency on parenteral support (PS)?

Yes. In clinical studies, GATTEX was proven to help adults and children 1 year of age and older with SBS on PS. **PS is any kind of nutrition and/or fluids that are given through a vein (intravenously).**



GATTEX reduced the weekly volume of PS



People treated with GATTEX achieved more time off of PS



Over time, some people achieved complete freedom from PS with GATTEX

In a 6-month study, 27 out of 43 adults treated with GATTEX reduced weekly PS volume by 20% or more vs 13 out of 43 on placebo, and 21 out of 39 achieved at least 1 day off PS per week vs 9 out of 39 on placebo. After 30 months of treatment, 10 out of 30 adults no longer needed PS. In a 6-month study, 18 out of 26 children treated with GATTEX reduced weekly PS volume by 20% or more, 10 out of 26 achieved a reduction of at least 1 day off PS per week, and 3 out of 26 no longer needed PS.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about GATTEX?

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.

Please see Important Safety Information on pages 18-19, click for full [Prescribing Information and Medication Guide](#), and discuss any questions with your doctor.



What should I tell my (or my child's) healthcare provider before using GATTEX?

Tell the doctor about all medical conditions, including if you or your child:

- 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, or kidneys

Can I (or my child) take other medications or supplements with GATTEX?

GATTEX may affect the way your body absorbs other medications. Your doctor should know about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using GATTEX with certain other medicines may affect each other, causing side effects. Other healthcare providers may need to change the dose of any oral medicines (medicines taken by mouth) you take while using GATTEX. Tell the doctor who gives you GATTEX if you will be taking a new oral medicine.

Throughout your GATTEX journey, it's important to know the medicines you take. Keep a list of them and share with your care team.

Can I take GATTEX if I am pregnant or breastfeeding?

Tell your doctor if you are pregnant, planning to become pregnant, breastfeeding or plan to breastfeed. Available data from case reports with GATTEX use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Pregnant women with short bowel syndrome are at risk for malnutrition, which is associated with adverse maternal and fetal outcomes. There is no information regarding the presence of GATTEX in human milk, the effects of GATTEX on the breastfed infant, or the effects of GATTEX on milk production.



ACTORS
PORTRAYAL

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about GATTEX? (continued)

Polyps in the colon (large intestine)

Polyps are growths on the inside of the colon. Your healthcare provider will have your colon checked for polyps within 6 months before starting GATTEX and have any polyps removed. Children and adolescents will be checked for blood in the stool before they start using GATTEX.

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.

Please see Important Safety Information on pages 18-19, click for full [Prescribing Information and Medication Guide](#), and discuss any questions with your doctor.

Gattex[®]
(teduglutide) for injection



GATTEX SIDE EFFECTS & MONITORING

What are the most common side effects of GATTEX?

In clinical studies, the most common side effects in adults were stomach area (abdomen) pain or swelling, nausea, cold or flu symptoms, skin reaction where the injection was given, vomiting, swelling of the hands or feet, and allergic reactions. Side effects seen in children and adolescents were similar. These are not all of the possible side effects of GATTEX.

What do I (or my child) do if side effects occur?

Tell your doctor right away if there are any bothersome side effects that do not go away. Always call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Will I (or my child) need extra monitoring or testing after starting GATTEX?

Yes, your doctor will check your colon for new polyps at the end of 1 year of using GATTEX. If no polyp is found, your doctor will check you for polyps as needed and at least every 5 years. Your doctor will also 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.

How long will I be on GATTEX?

Short bowel syndrome is a lifelong condition that results in chronic malabsorption. GATTEX is a medicine that can help you reduce and even eliminate the need for parenteral support (PS). It's important to continue taking your medicine as prescribed. Do not stop taking GATTEX without consulting your healthcare team.



ROY,
GATTEX PATIENT

BETSY,
GATTEX PATIENT

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about GATTEX? (continued)

Blockage of the bowel (intestines)

A bowel blockage keeps food, fluids, and gas from moving through the bowels in the normal way. Tell your healthcare provider right away if you have any of these symptoms of a bowel or stomal 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 a blockage is found, your healthcare provider may temporarily stop GATTEX.

Please see Important Safety Information on pages 18-19, click for full [Prescribing Information and Medication Guide](#), and discuss any questions with your doctor.





HOW TO USE GATTEX

How do I (or my child) use GATTEX?

GATTEX is a once-daily injection adults can self-administer once trained by a healthcare professional. Self-administration by children or adolescents is not recommended.

Where should GATTEX be administered?

GATTEX is an under the skin (subcutaneous) injection and should be injected either in the 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 inject GATTEX. Read the Instructions for Use for detailed instructions on preparing and injecting a dose of GATTEX.

How do I learn to administer GATTEX?

After training from your doctor or injection training nurse, most patients/caregivers can self-inject. The doctor or nurse should explain how to prepare, measure your dose, and give your injection of GATTEX the right way.

If you cannot give yourself the injection, then ask your doctor or a nurse to help you or ask someone who has been properly trained.

For pediatric patients, GATTEX should be injected by:

- A doctor or nurse, or
- A parent or adult caregiver who has been trained by a healthcare professional

How quickly do I need to inject once I've reconstituted GATTEX?

GATTEX must be injected within 3 hours after you mix it with the Diluent.

What supplies are needed when I use GATTEX?

The GATTEX kit contains: Syringes prefilled with Diluent, which is sterile water that's used to dilute your injection, 22-gauge 1½-inch needles, 5-mg vials of GATTEX, 1-mL plastic dosing syringes with 26-gauge ⅝-inch needles attached, needles to attach to the Diluent syringe, and alcohol swab pads. You will also need a sharps disposal container and bandages, which are not included in the kit. Your healthcare provider will tell you how many vials of GATTEX you will need for your injection based on your dosage.

What should I do if I miss a dose?

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. And if you use more than 1 dose, call your doctor right away.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about GATTEX? (continued)

Swelling (inflammation) or blockage of your gallbladder or pancreas

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
- a change in your stools
- nausea
- vomiting
- dark urine
- yellowing of your skin or the whites of your eyes

Please see Important Safety Information on pages 18-19, click for full [Prescribing Information and Medication Guide](#), and discuss any questions with your doctor.



HOW TO STORE GATTEX

Does GATTEX need to be refrigerated?

No, you can store the GATTEX vial at room temperature up to 77°F (25°C). Do not freeze GATTEX. GATTEX must be injected within 3 hours after you mix it with the Diluent. Use the GATTEX powder by the expiration date on the “Use By” sticker on the kit.

Can I use GATTEX that is leftover after administering it?

No, use GATTEX within 3 hours after mixing it. Safely 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. Keep GATTEX and all medicines out of the reach of children.

How do I travel with GATTEX?

Make sure to pack enough supplies when traveling with GATTEX. And keep them at room temperature. If you are flying, make sure to have the TSA letter (you’ll find this in your welcome kit) on hand that explains your condition and the medication required. Keep the letter in your carry-on luggage. This way, you’ll be prepared if you are questioned at security checkpoints or during customs screenings.



PEGGY,
GATTEX PATIENT

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about GATTEX? (continued)

Fluid overload

Your healthcare provider will check you for too much fluid in your body. Too much fluid in your body may lead to heart failure, especially if you have heart problems. 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.

Please see Important Safety Information on pages 18-19, click for full [Prescribing Information and Medication Guide](#), and discuss any questions with your doctor.





ONEPATH PRODUCT SUPPORT & RESOURCES

How can OnePath help me?

Patient Support

From the moment you or your loved one enrolls in OnePath, a dedicated Patient Support Manager (PSM) will assist with access to treatment and support.

You'll also be introduced to an Onboarding & Access Specialist (OAS) in your area, who will be one of your primary contacts as you get started on therapy.

Delivery of Treatment and Training

Once you have connected with your or your loved one's PSM, they will help arrange delivery of GATTEX to you or the location where treatment

is received and schedule training with a nurse educator to show you and/or your caregiver how to prepare, measure specific doses, and administer GATTEX according to the prescribing information, if requested by your doctor.

Insurance Coverage

Your dedicated PSM can also work with you one-on-one to guide you through the process of understanding your insurance coverage.

They will initiate a benefits investigation to determine your insurance coverage and the financial options that will determine the cost of GATTEX to you.

OnePath provides product support services for eligible GATTEX patients. Support services like:



Navigating health insurance



Providing information about financial assistance options



Working with the specialty pharmacy to coordinate in-home product delivery



Coordinating free injection training if requested by your doctor



Providing ongoing education throughout the treatment journey

ADDITIONAL SUPPORT & RESOURCES

Are there real stories available about living with SBS and GATTEX?

Yes. Go to [GATTEX.com/resources-support](https://www.gattex.com/resources-support) to watch and listen to people with short bowel syndrome (SBS) share their stories of what it's like to live with the condition and how they were able to achieve less time on parenteral support (PS) with GATTEX.

Are there programs available to speak with others living with SBS?

SBS Patient Ambassadors are adults with short bowel syndrome who know what it's like to be dependent on PS and who have experience taking GATTEX. Through SBS Connect, you can speak with someone who will share their journey from diagnosis to treatment. Also, ask about the Speaker program available to all patients or the Mentor program available only for adults with SBS.

Sign up to receive resources and connect with Patient Ambassadors at [GATTEX.com/resources-and-support](https://www.gattex.com/resources-and-support) or call 1-844-247-1638.

Are there other SBS support networks? If so, how can I access them?

There are many nonprofit organizations out there that can help people with SBS and their loved ones form important connections with others.

THE CAREGIVER ACTION NETWORK (CAN) goal is to improve the quality of life for caregivers by offering free education, peer support, and resources. [caregiveraction.org](https://www.caregiveraction.org)

THE NATIONAL ORGANIZATION OF RARE DISORDERS (NORD) is a patient advocacy organization committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and service. [rarediseases.org](https://www.rarediseases.org)

THE OLEY FOUNDATION helps those living with home intravenous nutrition and tube feeding. [oley.org](https://www.oley.org)

THE UNITED OSTOMY ASSOCIATIONS OF AMERICA (UOAA) supports, empowers, and advocates for people who have had or who will have ostomy or continent diversion surgery. [ostomy.org](https://www.ostomy.org)

Takeda is not responsible for the content of any website not owned by Takeda.

Please see Important Safety Information on pages 18-19, click for full [Prescribing Information and Medication Guide](#), and discuss any questions with your doctor.





FOR PARENTS OR CAREGIVERS OF CHILDREN TAKING GATTEX

Is GATTEX safe to use in children?

Yes, GATTEX can be used in children 1 year of age and older with Short Bowel Syndrome (SBS) who need additional nutrition or fluids from intravenous (IV) feeding (parenteral support).

My child has started gaining weight, do they need a different GATTEX dose?

Maybe. It's important to let your child's doctor know if there are any changes in your child's body weight. The doctor will calculate the appropriate dose based on your child's new weight.

What information should my child's school know about GATTEX?

It is important that your child's school understands their condition and what support your child might need. Write a letter or have a face-to-face conversation explaining SBS, your child's limitations, their medications and parenteral support (PS). Also make sure to cover topics like what to do in an emergency, and how to handle symptoms your child may have. Most importantly, encourage them to treat your child as they would any other child.



My notes

If you have additional questions, please speak to your healthcare team.

IMPORTANT SAFETY INFORMATION

The most common side effects of GATTEX in adults include:

- stomach area (abdomen) pain or swelling
- nausea
- cold or flu symptoms
- skin reaction where the injection was given
- vomiting
- swelling of the hands or feet
- allergic reactions

The side effects of GATTEX in children and adolescents are similar to those seen in adults. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Please see Important Safety Information on pages 18-19, click for full [Prescribing Information and Medication Guide](#), and discuss any questions with your doctor.



ACTORS
PORTRAYAL

IMPORTANT SAFETY INFORMATION

What is GATTEX?

GATTEX® (teduglutide) for subcutaneous injection is a prescription medicine used in adults and children 1 year of age and older with Short Bowel Syndrome (SBS) who need additional nutrition or fluids from intravenous (IV) feeding (parenteral support). It is not known if GATTEX is safe and effective in children under 1 year of age.

What is the most important information I should know about GATTEX?

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. Your healthcare provider will have your colon checked for polyps within 6 months before starting GATTEX and have any polyps removed. Children and adolescents will be checked for blood in the stool before they start using GATTEX.

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. Tell your healthcare provider right away if you have any of these symptoms of a bowel or stomal 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 a blockage is found, your healthcare provider may temporarily stop GATTEX.

Swelling (inflammation) or blockage of your gallbladder or pancreas

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
- a change in your stools
- nausea

- vomiting
- dark urine
- yellowing of your skin or the whites of your eyes

Fluid overload

Your healthcare provider will check you for too much fluid in your body. Too much fluid in your body may lead to heart failure, especially if you have heart problems. 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.

The most common side effects of GATTEX in adults include:

- stomach area (abdomen) pain or swelling
- nausea
- cold or flu symptoms
- skin reaction where the injection was given
- vomiting
- swelling of the hands or feet
- allergic reactions

The side effects of GATTEX in children and adolescents are similar to those seen in adults. 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 about all your medical conditions, including if you or your child:

- 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
- 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 should not breastfeed during treatment with GATTEX. Talk to your healthcare provider about the best way to feed your baby while using GATTEX.

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 (medicines taken by mouth) 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.





Learn more about how **GATTEX**
may help at [GATTEX.com](https://www.gattex.com)

What is GATTEX?

GATTEX® (teduglutide) for subcutaneous injection is a prescription medicine used in adults and children 1 year of age and older with Short Bowel Syndrome (SBS) who need additional nutrition or fluids from intravenous (IV) feeding (parenteral support). It is not known if GATTEX is safe and effective in children under 1 year of age.

What is the most important information I should know about GATTEX?

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 18-19, click for full [Prescribing Information and Medication Guide](#), and discuss any questions with your doctor.



GATTEX and the GATTEX logo are registered trademarks of Shire-NPS Pharmaceuticals, Inc., a Takeda company. OnePath and the OnePath logo are registered trademarks of Shire, a Takeda company. TAKEDA and the TAKEDA logo are registered trademarks of Takeda Pharmaceutical Company Limited.

©2021 Takeda Pharmaceuticals U.S.A., Inc. All rights reserved. US-TED-0935v1.0 09/21