



LEARN MORE ABOUT GATTEX[®] FOR ADULTS

Please see Important Safety Information on pages 12 and 13 and for additional safety information, click here for full [Prescribing Information](#) and [Medication Guide](#), and discuss any questions with your doctor.

You may have a lot of questions and it's important for you to be well informed. So make sure to ask your doctor any questions you have and continue to learn as much as possible.

Explore this guide to learn more about:



How GATTEX works



Building a support network



Clinical study results



Helpful resources



Talking with your doctor



Making health goals

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.

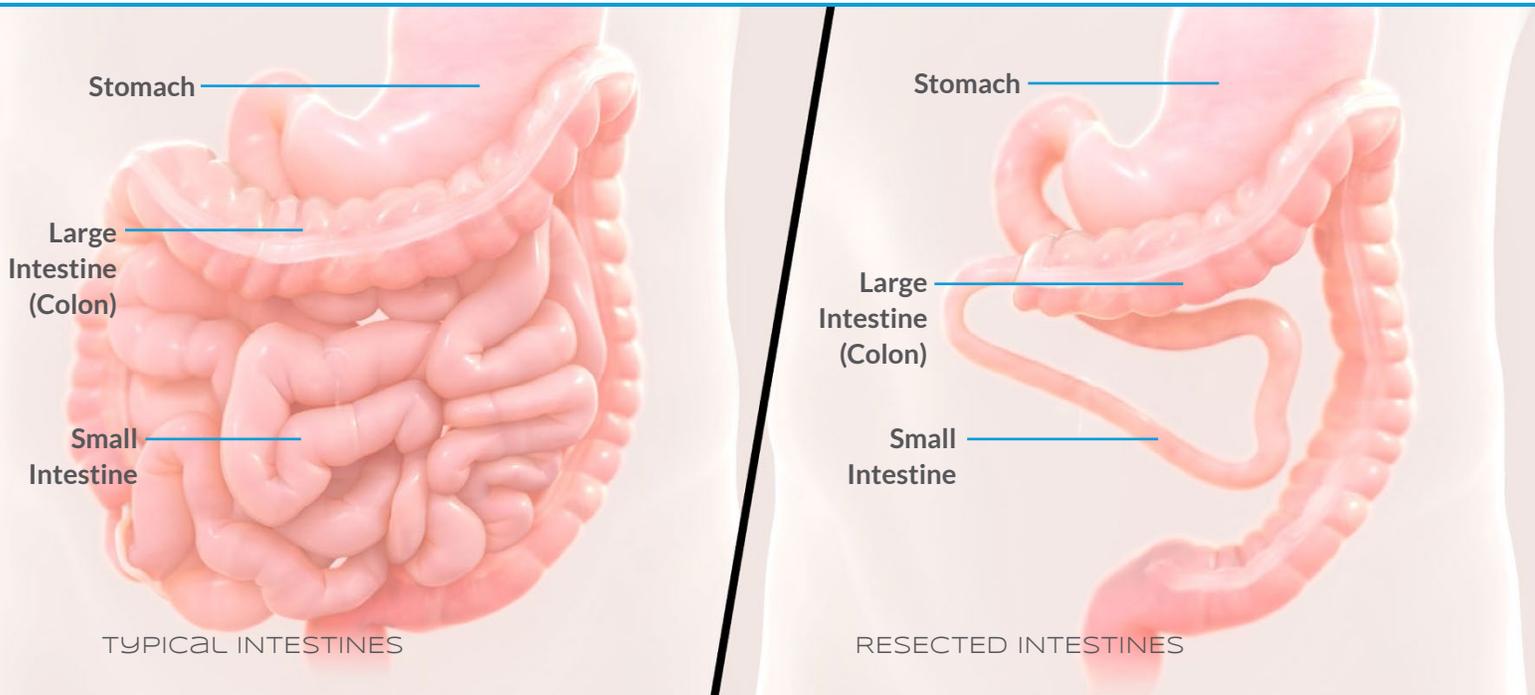
Important Safety Information

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

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

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Short Bowel Syndrome (SBS) is a rare, serious, and chronic malabsorption condition where a person is unable to absorb enough nutrients and fluids from what they eat and drink due to the surgical removal of a large part of their intestines.



The images in this brochure do not show exact models of the human body.
The intestines of each person with SBS are different and the images used here may not represent your intestinal anatomy.

- The intestines absorb the fluids and nutrients that you eat and drink
- SBS can happen when a large part of the intestines are surgically removed because of disease or injury
- If your intestines do not adapt well after a section is removed, you may not be able to get enough nutrients and fluids from your diet and may need to receive parenteral support (PS) to meet your nutritional needs

DID YOU KNOW?

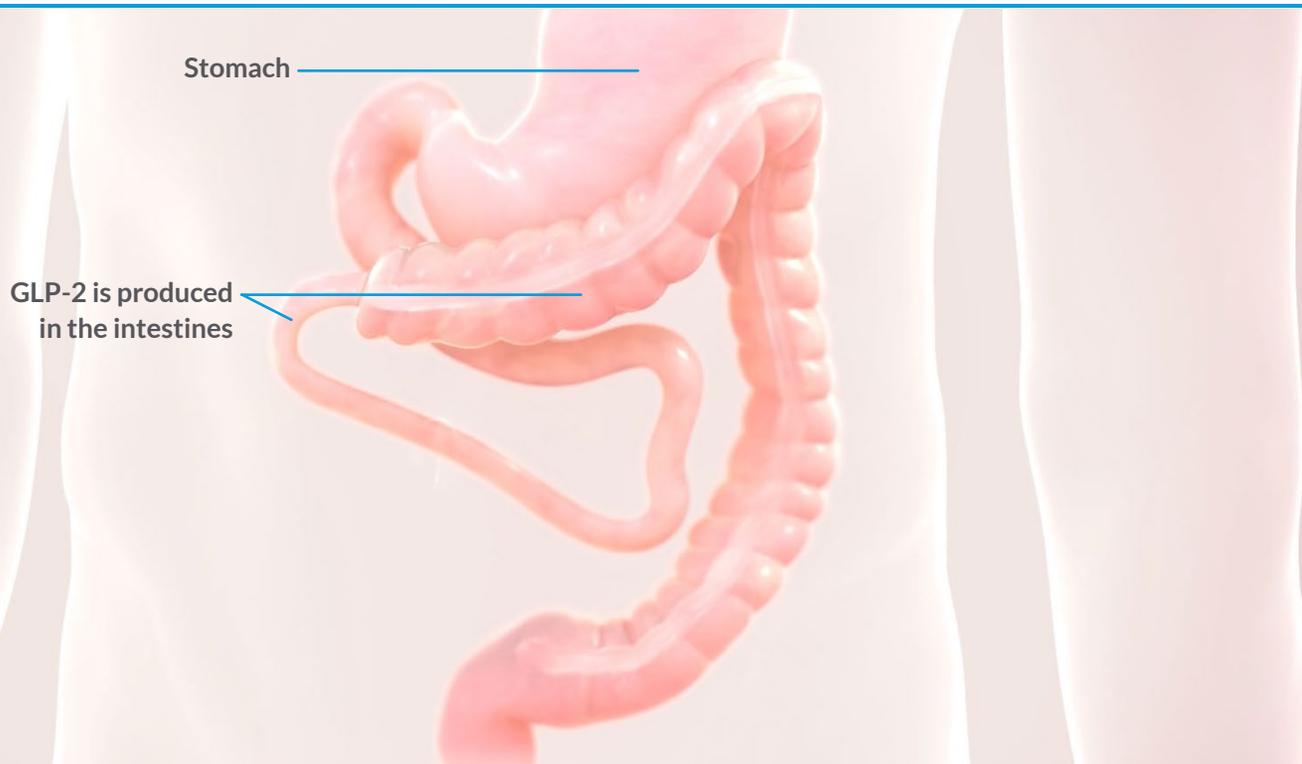
Parenteral support refers to nutrition and fluids that are given to you through your veins and includes both nutrition and intravenous (IV) fluids or hydration.

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THE ROLE OF A HORMONE IN ABSORBING NUTRIENTS

Many people are still able to absorb fluids and nutrients after a section of their intestine is removed (resection) because the intestines that are left can adapt over time.

- The intestine makes hormones that help increase the surface area of the intestinal wall, making it easier for your body to absorb fluids and nutrients
- One of these hormones is called glucagon-like peptide-2 (GLP-2)
- GLP-2 helps the intestine increase its surface area for better absorption of fluids and nutrients



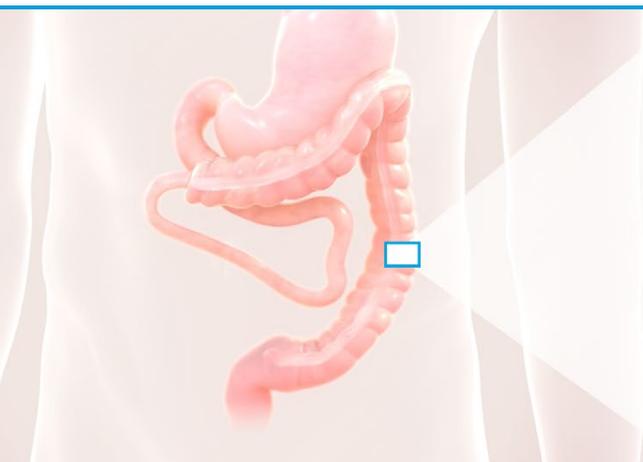
In many people with SBS, the part of the intestine that makes GLP-2 has been removed. The intestine that is left is not as good at absorbing fluids and nutrients, possibly because GLP-2 is missing. In some people with SBS, the intestine that is left makes GLP-2, but it may not be enough to help increase the intestine surface area to absorb all of the fluids and nutrients that the body needs.

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DID YOU KNOW?

GATTEX works like GLP-2. In fact, it's the first and only GLP-2-based prescription medication for treating adults and pediatric patients aged 1 year and above with SBS who need additional nutrition or fluids from intravenous (IV) feeding, also known as parenteral support.

A study showed GATTEX increased the surface area in the remaining bowel and enhanced fluid absorption in adults with SBS.



Increased villus height and crypt depth of the intestinal mucosa.



Individual results may vary.

Explore the pharmacodynamics study details

The ability of GATTEX to improve the amount of fluids absorbed by the intestines was studied in 17 adults with SBS. People in the study received GATTEX for 21 days. They each took daily doses of either 0.03, 0.10, or 0.15 mg/kg via injections administered under the skin into the stomach area (abdomen). All the people in this study knew they were taking GATTEX.

All of the doses studied, except for the 0.03 mg/kg once-daily dose, resulted in enhanced absorption of fluid by the intestines – approximately 750 to 1000 mL per day – and increased the surface area of the intestines.*

*The recommended dosage of GATTEX for both adults and pediatric patients is 0.05 mg/kg once daily by subcutaneous injection. The recommended dosage in adult and pediatric patients with moderate and severe renal impairment and end-stage renal disease (estimated glomerular filtration rate (eGFR) less than 60 mL/min/1.73 m²) is 0.025 mg/kg once daily. Please see the full Prescribing Information for complete Dosage and Administration information.

Important Safety Information

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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.

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What would taking less weekly PS mean to you?

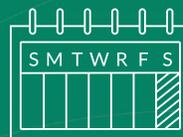
GATTEX was studied in a 6-month clinical trial of 86 adult patients who needed to use PS at least 3 times a week for at least 1 year. GATTEX helped the majority of patients:



Reduce weekly PS volume

GATTEX 63% reduced PS by 20% or more

Placebo 30% reduced PS by 20% or more



Get more day(s) off weekly PS

GATTEX 54% achieved at least 1 day off PS

Placebo 23% achieved at least 1 day off PS

Individual results may vary.

Important Safety Information

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

GATTEX may cause serious side effects, including:

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.

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More adult patients responded to GATTEX over time

GATTEX was also studied in a 24-month study. 76 of the 78 patients who completed the first study decided to participate in the extension study. They were joined by an additional 12 adults who were receiving PS at least 3 times a week for at least 1 year, for a total of 88 participants.

All of the people in this study knew they were taking GATTEX.



After 24 months:

55% reduced PS
by 20% or more

After 30 months:

93% reduced PS
by 20% or more

30 patients completed a total of 2.5 years of GATTEX treatment. (They took GATTEX in study 1 and GATTEX in study 2.)
29 patients completed 2 years of GATTEX treatment. (They took placebo in study 1, then GATTEX in study 2.)

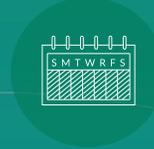
In the same clinical trial, GATTEX helped patients get more day(s) off weekly PS. After completing 30 months of GATTEX treatment:



70% achieved at least
1 day off per week
(21 out of 30 patients)



60% achieved at least
3 days off per week
(18 out of 30 patients)



33% weaned off PS
completely
(10 out of 30 patients)

Individual results may vary.

Important Safety Information

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

GATTEX may cause serious side effects, including:

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
- vomiting
- stomach area (abdomen) pain or swelling
- swelling and blockage of your stoma opening, if you have a stoma
- nausea

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

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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.**
- **Do not stop taking GATTEX without consulting your healthcare provider.**
- 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 download Instructions for Use.

Go to: www.gattex.com/getting-started/

TAKE AN ACTIVE ROLE IN YOUR TREATMENT JOURNEY

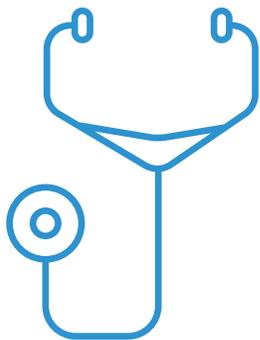
Suggested questions to ask your healthcare provider about GATTEX

1. What is the most important information I should know about GATTEX?
2. What types of tests and procedures will I need before starting GATTEX and while taking GATTEX?
3. How should I use GATTEX?
4. What are the possible risks and side effects of GATTEX?
5. How should I store GATTEX?
6. Will GATTEX affect the medications I'm currently taking?
7. What should I do if I miss a dose?
8. Will my diet and PS needs change while I am taking GATTEX?
9. How will we evaluate how much fluid volume I need?

Remember that you play an important role in managing your treatment journey.

- Talk to your dietitian about your daily food and fluid intake
- Ask your healthcare provider any questions you may have about your treatment plan
- Take all your medications as prescribed by your healthcare providers
- Follow your healthcare provider's instructions, which may include asking you to keep track of how you are doing. You may need to monitor your daily urine output, what you are eating, how much you weigh, etc.

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BUILDING A SUPPORT NETWORK

Many different people can help provide support throughout your treatment journey. Your support network may be made up of several different teams:

Your healthcare team

When it comes to providing support, your healthcare team plays a crucial role. The team may include your:

- Primary care doctor
- Gastroenterologist
- Surgeon
- Dietitian
- Home healthcare nurse, who has been specially trained on GATTEX
- Pharmacist(s)



Your OnePath team

OnePath is a free product support program for GATTEX. After you've been prescribed GATTEX and deemed eligible, you will meet with a local OnePath Onboarding & Access Specialist who will work closely with you and your doctor during the first few months of treatment. OnePath also matches you with a dedicated Patient Support Manager. After you've been on treatment for several months, your Patient Support Manager will be your main point of contact at OnePath. He or she will check in with you periodically to ensure you don't have any issues accessing your treatment.

Your caregivers

You may also have family members or loved ones who lend a hand on a regular basis. These caregivers can be a great source of both practical and emotional support.

HELPFUL RESOURCES

For more information about GATTEX, talk with your healthcare provider and visit www.GATTEX.com. You can also check out the websites below for resources, information on patient support groups, and other opportunities to connect with the SBS community.

Patient Support

- American Society of Parenteral and Enteral Nutrition (ASPEN)
www.nutritioncare.org
- Crohn's and Colitis Foundation
www.crohnscolitisfoundation.org
- International Foundation for Functional Gastrointestinal Disorders (IFFGD)
www.iffgd.org
- National Organization for Rare Disorders (NORD)
www.rarediseases.org
- The Oley Foundation
www.oley.org
- United Ostomy Associations of America (UOAA)
www.ostomy.org

Caregiver Organizations

- Caregiver Action Network (CAN)
www.caregiveraction.org
- Family Caregiver Alliance (FCA)
www.caregiver.org
- National Alliance for Caregiving (NAC)
www.caregiving.org

Some of the websites listed here allow for free exchange of information (for example, chat rooms and forums). Takeda does not sponsor or endorse this free exchange of information. Takeda is not responsible for the content or services provided by any websites that are not owned by Takeda. Websites that are not owned by Takeda are governed by their own policies and guidelines, including privacy policies.

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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
- vomiting
- stomach area (abdomen) pain or swelling
- swelling and blockage of your stoma opening, if you have a stoma
- nausea

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
- nausea
- chills
- vomiting
- fever
- dark urine
- a change in your stools
- 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.

Important Safety Information continues on the next page and for additional safety information, click here for full [Prescribing Information](#) and [Medication Guide](#), and discuss any questions with your doctor.

Important Safety Information (continued)

The most common side effects of GATTEX in adults include:

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

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.

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Gattex[®]
(teduglutide) for injection



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