

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 additional Important Safety Information throughout, click for full <u>Prescribing</u> <u>Information and Medication Guide</u>, and discuss any questions with your doctor.



SBS is a serious and chronic malabsorption disorder

Short bowel syndrome (SBS) occurs when parts of the intestine are removed surgically and the remaining intestine may not be able to absorb enough nutrients from food and drink

SBS results in malabsorption. It puts people at risk for:



There are multiple factors a doctor may use to determine an SBS diagnosis, not just the length of remaining bowel

SBS management

Important treatment goals for people with SBS include:

- Maintaining essential nutrition and hydration
- Helping the intestine adapt so it can properly digest nutrients and fluids
- Improving daily life by supporting healthy work, sleep, and social habits
- Reducing or eliminating the need for long-term parenteral support

Many people with SBS require parenteral support (PS)

PS is any kind of nutrition and/or fluids that are given through a vein (intravenously). Based on your personal needs, PS can include a mix of ingredients, such as proteins, carbohydrates, fats, vitamins, and minerals.

PS requirements can vary based on your nutritional needs:

LESS NUTRIENTS Intravenous (IV) fluids, a mix of electrolytes MORE NUTRIENTS Total Parenteral Nutrition (TPN), a complete mix of liquid nutrients

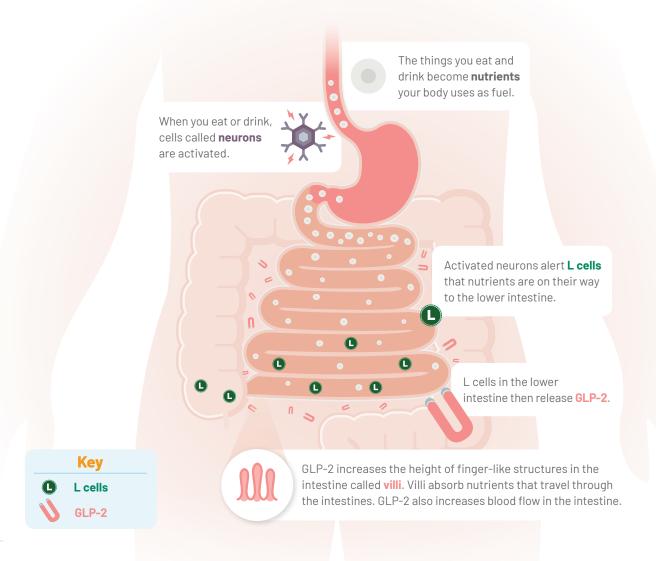
Long-term use of PS is not recommended because it can lead to infections and long-term complications

PS provides essential nutrition but does not help the intestine absorb nutrients on its own

Understanding the importance of the hormone GLP-2

GLP-2, short for glucagon-like peptide-2, is a hormone produced in the intestine that helps the body absorb nutrients and fluids

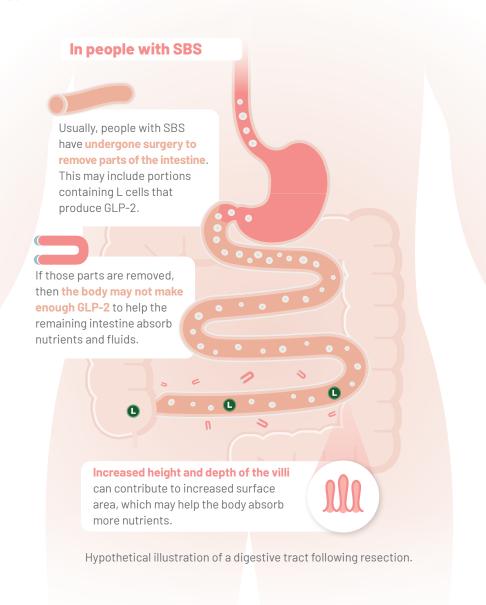
Hormones are chemical messengers that help your body in many different ways.



GLP-2 impacts the way the body absorbs nutrients and fluids

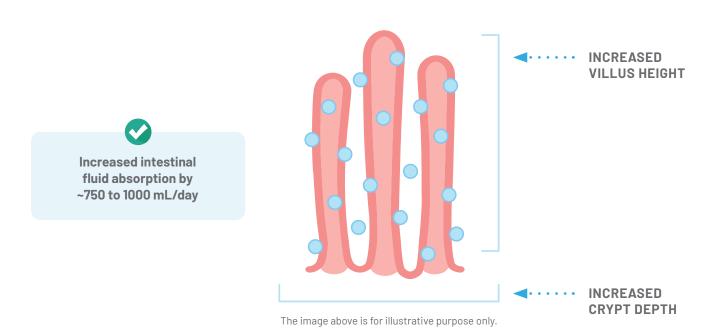
People with short bowel syndrome (SBS) may not produce enough GLP-2 in their body

Without enough GLP-2, the nutrients and fluids your body absorbs from the things you eat and drink can be limited.



GATTEX is the first and only treatment that works like the GLP-2 the body normally makes on its own

In a study of adults, GATTEX was proven to help the remaining intestine absorb more fluid*



^{*}The ability of GATTEX to improve the amount of fluid absorbed by the intestines was studied in 17 adults with SBS. Participants in the study received GATTEX for 21 days. All the participants in this study knew they were taking GATTEX. They each took daily doses of either 0.03, 0.10, or 0.15 mg/kg by injection (0.6 to 3 times the recommended dose). The injections were administered under the skin in the stomach area (abdomen). 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.

IMPORTANT SAFETY INFORMATION

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

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.

GATTEX may reduce the need for PS

In clinical studies, GATTEX was proven to help adults with short bowel syndrome (SBS) on parenteral support (PS)



VOLUME

GATTEX reduced the weekly volume of PS.



TIME

People treated with GATTEX achieved more time off of PS.



FREEDOM

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.

Less time on PS could mean more time for:



Examples of how some patients may spend their time with reduced PS requirements are for illustrative purposes only. Be sure to discuss your medical circumstances and activities with your doctor.



GATTEX was evaluated in 2 clinical studies



STEPS: This was a 6-month study of **86 adults** with short bowel syndrome (SBS) who needed parenteral support (PS) at least 3 times per week for at least 1 year. Of the 86 participants, 43 received GATTEX and 43 received placebo once a day. The goal was to see if significantly more people treated with GATTEX compared with those who received placebo achieved a reduction in weekly PS volume of at least 20% at Weeks 20 and 24. The study also evaluated safety.



STEPS-2: This was a 24-month study of **88 adults** with SBS. 76 people had participated in STEPS (37 received GATTEX, 39 received placebo) and were enrolled in STEPS-2 after STEPS ended. 12 people had not participated in STEPS and had never been treated with GATTEX before. In STEPS-2, all participants were treated with GATTEX once daily and were told that they were being treated with GATTEX.

Patient baseline characteristics in STEPS:

	Average	Range
Age	50 years	18-82 years
Estimated small bowel length	77.3 cm	5-343 cm
Length of time on PS	6 years	1-26 years
Prescribed days per week on PS	5.73 days	3-7 days
Infusion volume	13 L/week	0.9-35 L/week

GATTEX has been prescribed for adults since 2012





Most adults needed less volume of PS with GATTEX

In clinical studies, GATTEX reduced the weekly volume of parenteral support (PS) by 20% or more

At 6 months with GATTEX

In people who completed 30 months of treatment with GATTEX

More than half

63% (27/43)

reduced their PS volume by 20% or more with GATTEX vs

30% (13/43) of people who received placebo



Almost all

93% (28/30)

reduced their PS volume by 20% or more with GATTEX

IMPORTANT SAFETY INFORMATION

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

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.

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.





Many adults spent less time on PS with GATTEX

In clinical studies, GATTEX helped adults achieve less time and fewer days on parenteral support (PS) each week

At 6 months with GATTEX

In people who completed 30 months of treatment with GATTEX

54% (21/39) achieved

at least 1 day off of PS per week with GATTEX

1/5

23% (9/39) of people who received placebo



60% (18/30) achieved

at least 3 days off of PS per week with GATTEX

IMPORTANT SAFETY INFORMATION

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

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
- 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.





Freedom from PS may be possible

Some adults taking GATTEX achieved complete freedom from parenteral support (PS) after 30 months of treatment*



10 out of 30 people

no longer needed PS

The time it took to achieve complete freedom ranged from about 7 to 30 months, with the average at approximately 20 months.

Not everyone who takes GATTEX will fully wean off of PS.

*In STEPS-2, participants were maintained on GATTEX even if they no longer required PS.

IMPORTANT SAFETY INFORMATION

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

GATTEX may cause serious side effects, including:

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





What to expect when taking GATTEX

It may take time for GATTEX to work. In clinical studies, some adults experienced improved results the longer they stayed on GATTEX

For some adults, they were able to reduce weekly parenteral support (PS) volume after about 1 month of treatment with GATTEX. For others, it took 12 months or longer of treatment with GATTEX. Some did not respond at all.

Things to keep in mind during your treatment journey:



Track your experience and keep detailed notes that you can use in conversations with your doctor.



Check in with your doctor about what you're experiencing and talk openly about it.



Continue taking GATTEX as long as your doctor recommends.

Everyone with short bowel syndrome (SBS) is unique, and your experience with GATTEX will be too

IMPORTANT SAFETY INFORMATION

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

GATTEX may cause serious side effects, including:

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 guickly (water weight), or you have trouble breathing.

GATTEX is self-administered once daily

GATTEX is an under-the-skin (subcutaneous) injection

There are a few things to know when taking GATTEX. **These are not all the steps**—be sure to refer to the full **Instructions for Use**.



Inject 1 time each day at the same time.



Inject in 1 of 3 areas:Stomach area,

either thigh, or either upper arm.



Use a different injection site each time.

Before you start GATTEX, you must receive administration training by a healthcare professional



Get to know more about GATTEX

Here are some easy ways to learn more about GATTEX and connect with the community:



SCAN THE OR CODE TO VISIT GATTEX.COM

With educational resources and discussion guides you can use with your doctor, **GATTEX.com** can help you stay informed.



SPEAK WITH OTHER PATIENTS THROUGH SBS CONNECT

Sign up to speak with an SBS Ambassador who will share their experience with short bowel syndrome (SBS) and GATTEX. To sign up, visit **SBSConnect.com** or call 1-844-247-1638.



ATTEND A GATTEX SPEAKER PROGRAM

Learn more about GATTEX from a healthcare expert and hear from someone living with SBS who has experience with GATTEX. Call 1-855-575-3819 to learn more and register for a program.



LIKE US ON FACEBOOK

Find us on Facebook at <u>Facebook.com/GATTEX</u> to learn more and connect with others in the SBS community.

Other resources are available

Sometimes it's helpful to hear from others who are going through the same things as you

Listed are some dedicated nonprofit organizations that support people with SBS*:

THE CAREGIVER ACTION NETWORK (CAN)

The CAN's goal is to improve the quality of life for caregivers by offering free education, peer support, and resources. **caregiveraction.org**

THE NATIONAL ORGANIZATION OF RARE DISORDERS (NORD)

The 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**

THE OLEY FOUNDATION

The Oley Foundation helps those living with home intravenous nutrition and tube feeding. oley.org

THE UNITED OSTOMY ASSOCIATIONS OF AMERICA (UOAA)

The UOAA supports, empowers, and advocates for people who have had or who will have ostomy or continent diversion surgery. **ostomy.org**



^{*}This information is provided as a resource and not intended to be an endorsement. Takeda is not responsible for the content of any website not owned by Takeda.

OnePath® is personalized product support



OnePath provides a range of product support services throughout your GATTEX treatment journey. From the moment you enroll in OnePath, your dedicated Patient Support Manager (PSM) will work with you one-on-one throughout your pathway to treatment and beyond. You'll also be introduced to an Onboarding & Access Specialist (OAS) in your area who will be one of your primary support persons as you start on your GATTEX therapy.

Your OnePath team is here to help you:



Navigate the health insurance process



Find information about financial assistance options



Connect with reimbursement education



Coordinate with your specialty pharmacy



Set up one-on-one injection training with a Certified Nurse Educator



Stay informed about additional resources



Access GATTEX by working with your healthcare team as needed

For more information about OnePath and how to enroll, talk to your healthcare professional or visit <u>GATTEX.com/resources-and-support</u>

Important Safety Information

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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.

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:

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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

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,

lell your healthcare provider about all your medical conditions including 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
- 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. <u>Visit www.fda.gov/medwatch</u> or call 1-800-FDA-1088.

Please click for full <u>Prescribing Information and Medication</u> <u>Guide</u>, and discuss any questions with your doctor.





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