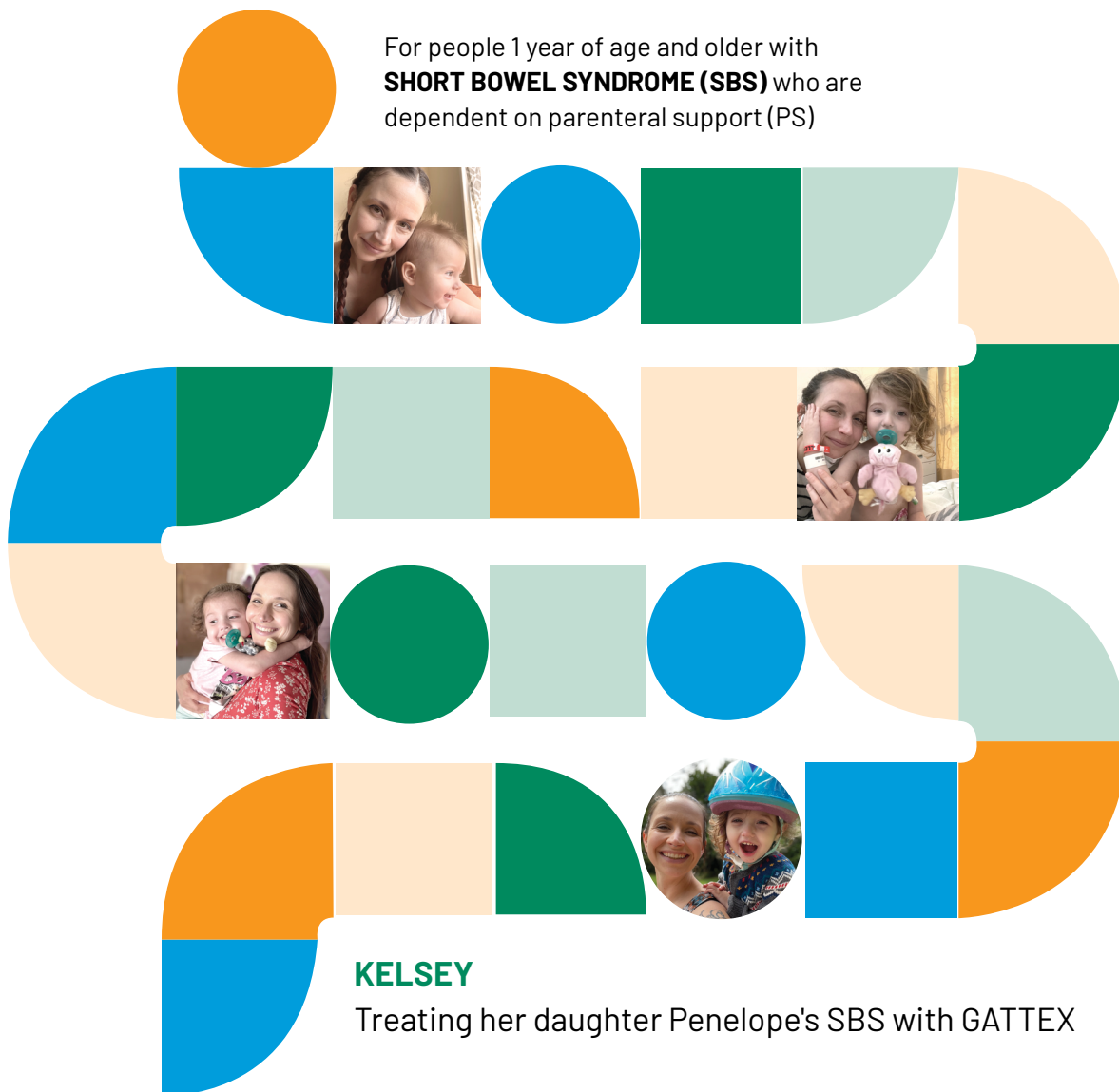


GATTEX KNOWS SBS

For people 1 year of age and older with
SHORT BOWEL SYNDROME (SBS) who are
dependent on parenteral support (PS)



KELSEY

Treating her daughter Penelope's SBS with GATTEX

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 intestines, blockage of the bowel (intestines), swelling (inflammation) or blockage of your gallbladder or pancreas, and fluid overload.

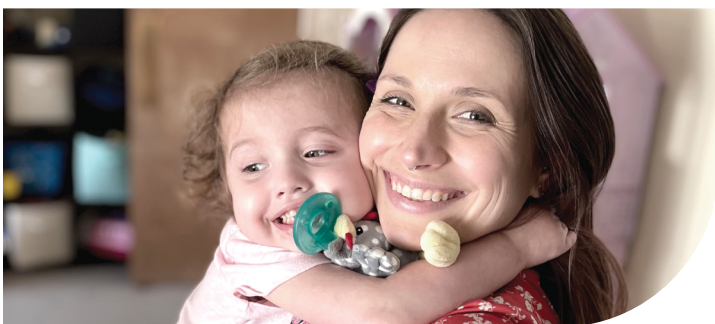
Please see additional Important Safety Information throughout
and click for full [GATTEX Prescribing Information](#).

Gattex
(teduglutide) for injection

GATTEX and Your Child with SBS



PENELOPE AND HER MOM, KELSEY, Treating her daughter Penelope's SBS with GATTEX



This brochure is built to help you. Caring for a child with SBS who is dependent on parenteral support (PS) presents many challenges.

How can GATTEX help? Throughout this brochure you will find information about how GATTEX works, clinical study data, personal stories, and resources for families managing SBS.

You're the bedrock, and we're here to support you and your family, because GATTEX knows SBS.

• 2012 •



First SBS-IF treatment approved for adults

• 2015 •



A support network for patients is created to help provide access to patients' prescribed Takeda treatment

• 2019 •



Pediatric approval for patients over 1 year of age

SBS-IF: short-bowel syndrome with intestinal failure.

IMPORTANT SAFETY INFORMATION

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 intestines

Polyps are growths on the inside of the intestines. For adult patients, your healthcare provider will have your colon and upper intestines 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 and upper intestines checked for polyps at the end of 1 year of using GATTEX.

Please see additional Important Safety Information throughout and click for full [GATTEX Prescribing Information](#).

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(teduglutide) for injection

About SBS and its Management

SBS is a serious and chronic malabsorption disorder. It is the result of physical loss and functional deficiency of portions of the intestine, primarily due to surgical resection.

Some important treatment goals



Lowering or eliminating the need for long-term PS and reducing complications over time



Helping the intestine adapt



Maintaining healthy levels of nutrition and hydration



What to ask about

Different people need different care. It's important to work with your doctor to set your child's treatment goals.

Scan or [click here](#) to learn more about SBS management

Parenteral Support

Parenteral support (PS) can provide fluids and/or nutrition. Depending on need, there are two types of PS:

- Intravenous (IV) fluids deliver necessary hydration along with a mix of electrolytes through a vein
- Total parenteral nutrition (TPN) can include a mix of proteins, carbohydrates, fats, vitamins, and minerals delivered through a central or peripheral line

PS does not increase intestinal absorption of essential nutrients.

Although PS is a life-saving intervention, long-term use of PS has been linked to kidney and liver issues as well as other health complications. It's important to discuss long-term treatment expectations and impacts with your child's healthcare provider.

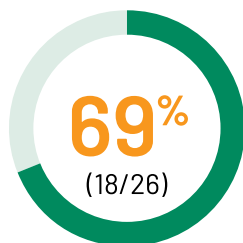
Reducing Volume of PS for Children with SBS



GATTEX WAS CLINICALLY PROVEN TO **REDUCE VOLUME OF PS***

At 6 months

with GATTEX



of children **reduced their weekly PS volume by 20% or more from baseline†**

with GATTEX



Children achieved a mean (average) **reduction of**

42%

(-23/mL/kg/day) in daily PS volume from baseline

Results are based on participant diary data.

*Results are presented for the 0.05 mg/kg/day dosage, which is the recommended dosage of GATTEX.

†Baseline average PS volume was 60 mL/kg/day.

GATTEX was evaluated in a clinical trial



In a 6-month study of 59 children (ages 1-17) with SBS who needed PS, the main goal was to determine the ability of GATTEX to reduce weekly PS volume by at least 20% from baseline to Week 24. The study also evaluated the average reduction of weekly PS volume from baseline, number of people who reduced PS administration by at least 1 day per week, the average change in hours dedicated to daily PS administration, the number of people who completely stopped PS, and safety.

IMPORTANT SAFETY INFORMATION (Cont'd)

Polyps in the intestines (Cont'd)

For pediatric patients, your healthcare provider will check for blood in the stool within 6 months before starting GATTEX. If there is blood in the stool, your healthcare provider will check your colon and upper intestines for polyps, and have any polyps removed. To keep using GATTEX, your healthcare provider will check for blood in the stool every year during treatment of GATTEX. If there is blood in the stool, your healthcare provider will check your colon and upper intestines for polyps. The colon will be checked for polyps at the end of 1 year of using GATTEX.

For adult and pediatric patients, if no polyp is found at the end of 1 year, your healthcare provider should check you for polyps as needed and at least every 5 years. If any new polyps are found, your healthcare provider will have them removed and may recommend additional monitoring. If cancer is found in a polyp, your healthcare provider should stop GATTEX.

Please see additional Important Safety Information throughout and click for full [GATTEX Prescribing Information](#).

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(teduglutide) for injection

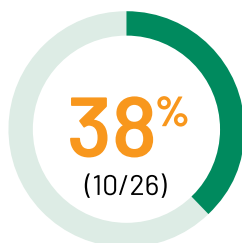
Reducing Time on PS for Children with SBS



GATTEX HELPED CHILDREN ACHIEVE **MORE TIME OFF PS[‡]**

At 6 months

with GATTEX



of children achieved at least
1 or more days off PS per week[§]

with GATTEX



Children achieved
3 fewer hours,
on average, of PS per day^{||}

[‡]Results are presented for the 0.05 mg/kg/day dosage, which is the recommended dosage of GATTEX.

[§]7 days/week average baseline PS requirement for GATTEX 0.05 mg/kg/day dosage group.

^{||}11 hours/day average baseline PS requirement for GATTEX 0.05 mg/kg/day dosage group.



“By her second birthday, GATTEX was a part of Penelope’s daily regimen. Over time, we gradually reduced her weekly PS volume.”

KELSEY

Treating her daughter Penelope's SBS with GATTEX
Individual results may vary.

IMPORTANT SAFETY INFORMATION (Cont'd)

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 additional Important Safety Information throughout and click for full [GATTEX Prescribing Information](#).

Gattex
(teduglutide) for injection

Weaning Off PS



Some children were able to wean off parenteral support (PS) after **6 months of treatment with GATTEX.**

At 6 months with GATTEX, **12% of children (3/26)** no longer needed PS and were able to wean off completely*

Not all children will fully wean off of PS.

*Results are presented for the 0.05 mg/kg/day dosage, which is the recommended dosage of GATTEX.

Remember, it takes time for GATTEX to work



For most children, GATTEX started to work at 6 months. It may take longer for some children, or they may not respond at all. It's important to consider that the time it takes for a reduction in weekly PS volume can vary from child to child.

IMPORTANT SAFETY INFORMATION (Cont'd)

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

GATTEX Side Effects

GATTEX may cause side effects. The side effects of GATTEX in children and adolescents are similar to those seen in adults. If you have any questions about side effects, whether before or during treatment, talk to your child's healthcare provider.

Below are the **most common side effects[†] (≥10%)** in 2 clinical studies of adult patients with SBS.

Side Effect	GATTEX (77 people)	Placebo (59 people)
Stomach area pain ¹	30%	22%
Nausea	23%	20%
Upper respiratory tract infection ²	21%	12%
Stomach area swelling	20%	2%
Skin reaction where injection was given ³	13%	12%
Vomiting	12%	10%
Swelling of the hands or feet ⁴	12%	7%
Allergic reactions ⁵	10%	7%

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 the gallbladder or pancreas, and fluid overload (too much fluid in your body).

If you experience any side effects, check in with your child's doctor. Continue taking GATTEX as long as your doctor recommends and work together to understand treatment expectations.

[†]Reported at a rate of at least 10% and greater than the placebo group.

¹Includes: Abdominal pain, upper abdominal pain, lower abdominal pain.

²Includes: Upper respiratory tract infection, nasopharyngitis, pharyngitis, sinusitis, laryngitis, rhinitis, viral upper respiratory tract infection.

³Includes: Injection site hematoma, injection site erythema, injection site pain, injection site swelling, injection site hemorrhage, injection site discoloration, injection site reaction, injection site rash.

⁴Includes: Fluid overload, peripheral edema, edema, generalized edema, fluid retention and jugular vein distension.

⁵Includes: Erythema, rash, dermatitis allergic, pruritus, rash macular, drug eruption, eyelid edema, flushing.

IMPORTANT SAFETY INFORMATION (Cont'd)

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 additional Important Safety Information throughout and click for full [GATTEX Prescribing Information](#).

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(teduglutide) for injection

Taking GATTEX

GATTEX must be administered by an adult.

Self-administration by children or adolescents is not recommended.

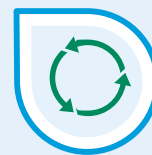
This is a general guide for taking GATTEX. Consult the full Instructions for Use located in the brochure pocket for more information.



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



See a step-by-step
administration video

Scan or [click here](#)
to watch video

How to prepare and inject a dose of GATTEX

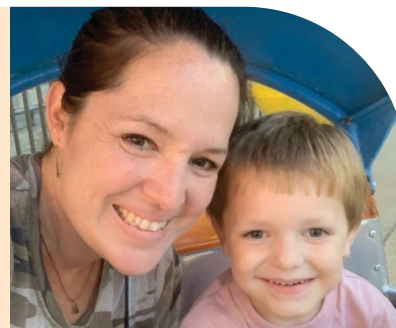
- GATTEX comes in a vial as a powder for injection that is used only 1 time (single-use vial)
- The powder must be mixed with sterile water for injection (a diluent) provided in a prefilled syringe before you inject it
- GATTEX must be injected within 3 hours after you mix it with the diluent

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

“These kids are amazing and so resilient. We may have to do things a little differently than others, but we figure it out.”

JODI

Treating her son Reid's SBS with GATTEX
Individual results may vary.



IMPORTANT SAFETY INFORMATION (Cont'd)

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

Please see additional Important Safety Information throughout and click for full [GATTEX Prescribing Information](#).

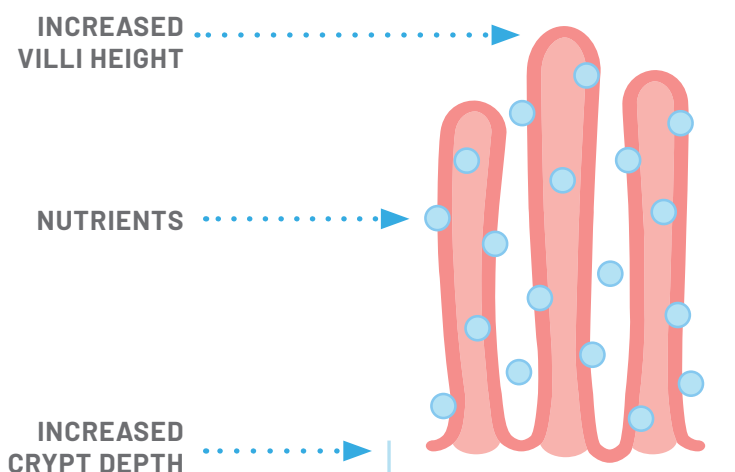
Gattex[®]
(teduglutide) for injection

How Does GATTEX Work?

GATTEX works like GLP-2 (glucagon-like peptide-2), a naturally occurring hormone in the body that increases villi height and crypt depth.

What are Villi? (in the intestine)

Villi are finger-like structures throughout the intestine that absorb nutrients. Less intestine means less villi. GATTEX increases the surface area (villus height/crypt depth) to help the body absorb more essential nutrition.*



The image above is for illustrative purpose only.



Scan to learn
more about
GLP-2 and GATTEX
or visit gattex.com

GATTEX increased fluid absorption within the intestine†

*The ability of GATTEX to improve the amount of fluid absorbed by the intestines was studied in 17 adult subjects 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 subcutaneous injection (0.6 to 3 times the recommended dose). The recommended dose is 0.05 mg/kg/day. 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 1,000 mL per day—and increased the surface area of the intestines.

† Approximately 750 to 1,000 mL/day.

IMPORTANT SAFETY INFORMATION (Cont'd)

The most common side effects of GATTEX in adults include (Cont'd):

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 additional Important Safety Information throughout and click for full [GATTEX Prescribing Information](#).

Gattex[®]
(teduglutide) for injection

Know What to Expect

Talk to someone about GATTEX

Connect directly with people living with, or caring for those who have short bowel syndrome. Learn about their experience with GATTEX and what that could mean for you and your loved ones.



Hear from a GATTEX caregiver

Meet Brianne, a devoted mother and caregiver to her son Liam, who lives with SBS

Scan or [click here](#) to watch video



SBSconnect

When you speak with an SBS Mentor, you'll hear from a caregiver who understands short bowel syndrome (SBS) and caring for a child who is dependent on PS. Connect with an SBS Mentor and share relatable experiences and stories. Plus, hear about their own personal experiences with GATTEX.

Scan to learn more or visit gattex.com/sbs-connect

This program is not intended for the purpose of disease diagnosis, to provide medical advice, or as a substitute for information that is provided to you by your physician. You should always discuss your medical condition and any questions you have with your physician.

This phone-based program enables adults, or caregivers managing children, with short bowel syndrome who are dependent on PS to speak to a mentor with SBS.

IMPORTANT SAFETY INFORMATION (Cont'd)

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:

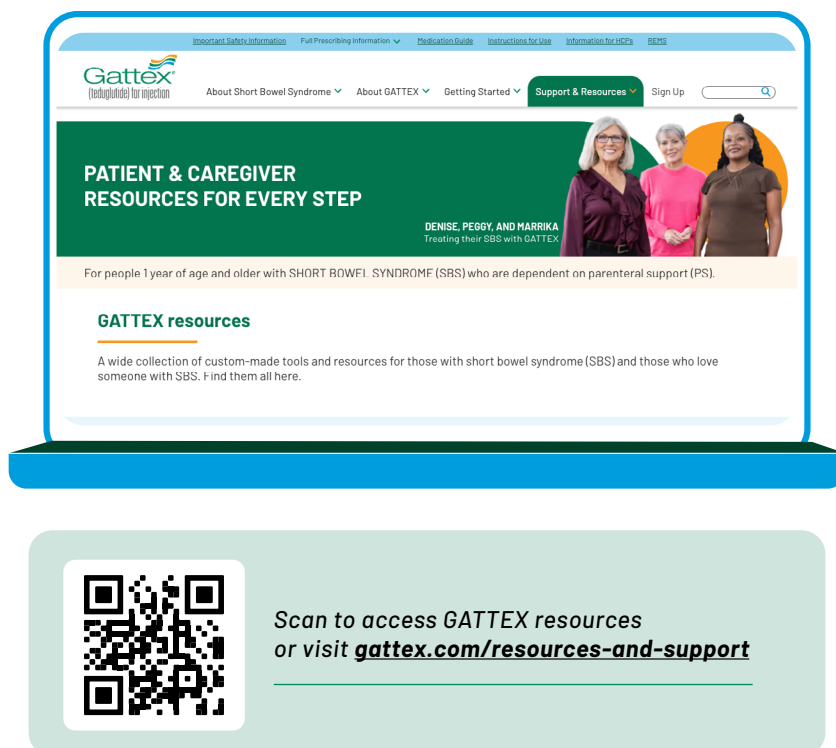
- have cancer or a history of cancer
- have or had polyps anywhere in your bowel (intestines) or rectum
- have heart problems
- have high blood pressure
- have problems with your gallbladder, pancreas, kidneys
- are pregnant or planning to become pregnant. It is not known if GATTEX will harm your unborn 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.

Please see additional Important Safety Information throughout and click for full [GATTEX Prescribing Information](#).

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Resources for You

We're here to help, by also providing multiple resources for you along your journey



Find valuable resources for patients and their caregivers, such as forms, links, programs, and information about GATTEX and SBS. No matter where you may be in your treatment journey, we're here for you.

IMPORTANT SAFETY INFORMATION (Cont'd)

What should I tell my healthcare provider before using GATTEX? (Cont'd)

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.

Additional Resources

These are nonprofit organizations that support patients with SBS and those who care for them.*

Caregiver Action Network (CAN)

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

[caregiveraction.org](https://www.caregiveraction.org) (855) 227-3640

The Oley Foundation

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

[oley.org](https://www.oley.org) (518) 262-5079

National Organization for Rare Disorders (NORD)

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) (202) 588-5700

United Ostomy Associations of America (UOAA)

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) (800) 826-0826

*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.



Connect with Specialists You Can Count on

When you're prescribed GATTEX, Takeda Patient Support is here for you. Shortly after enrolling, you'll receive a call from us to welcome you to the program. We'll let you know what to expect and explain how we can assist you. We're here to address your questions and concerns and to help get you the answers, resources, and tools you may need along the way.

WE CAN ALSO:



Enroll you in the Takeda Patient Support Co-Pay Assistance Program, if you qualify[†]



Arrange for nursing support if you have questions about your condition and your prescribed GATTEX treatment



Provide you with tips and timely information throughout your GATTEX treatment



Direct you to community support resources and education



Help you receive your treatment when you need it



NEED ASSISTANCE?

Our support specialists are never more than a tap or a call away—**1-866-888-0660, Monday through Friday, 8:30 AM to 8 PM ET.**

Not enrolled? You can join Takeda Patient Support in a few simple steps at TakedaPatientSupport.com/gattex. If English is not your preferred language, let us know. We may be able to assist you in the language of your choosing.

[†]To be eligible, you must be enrolled in Takeda Patient Support and have commercial insurance. Other terms and conditions apply. Call us for more details.

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

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 intestines

Polyps are growths on the inside of the intestines. For adult patients, your healthcare provider will have your colon and upper intestines 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 and upper intestines checked for polyps at the end of 1 year of using GATTEX.

For pediatric patients, your healthcare provider will check for blood in the stool within 6 months before starting GATTEX. If there is blood in the stool, your healthcare provider will check your colon and upper intestines for polyps, and have any polyps removed. To keep using GATTEX, your healthcare provider will check for blood in the stool every year during treatment of GATTEX. If there is blood in the stool, your healthcare provider will check your colon and upper intestines for polyps. The colon will be checked for polyps at the end of 1 year of using GATTEX.

For adult and pediatric patients, if no polyp is found at the end of 1 year, your healthcare provider should check you for polyps as needed and at least every 5 years. If any new polyps are found, your healthcare provider will have them removed and may recommend additional monitoring. 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

IMPORTANT SAFETY INFORMATION (Cont'd)

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
- 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.

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

Reduce Dependence on PS with GATTEX

In clinical studies of pediatric patients with SBS:



VOLUME

GATTEX reduced children's weekly volume of PS*



TIME

Children treated with GATTEX achieved more time off of PS*



FREEDOM

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

*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.

REID AND HIS MOM, JODI

Treating her son Reid's SBS with GATTEX



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.



VISIT
GATTEX.COM
OR SCAN HERE

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 intestines, blockage of the bowel (intestines), swelling (inflammation) or blockage of your gallbladder or pancreas, and fluid overload.

Please see additional Important Safety Information throughout and click for full [GATTEX Prescribing Information](#).



With nearly 30 years of experience in gastroenterology, Takeda continues its commitment to GI patients

Gattex®
(teduglutide) for injection