

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.

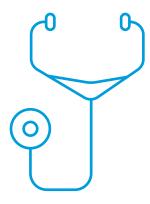


What is the most important information I should know about GATTEX?

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.



CONVERSATION GUIDE



If you're ready to know if GATTEX could be an option for you, the next step is to talk with your doctor. Here are some questions that can help guide your conversation. Take this list with you, add your own questions, and ask your doctor to help you understand the potential benefits and risks of treating with GATTEX.

1. What volume of parenteral support (PS) do I currently require?

2. How often do I infuse nutrients or fluids? How long does it take?

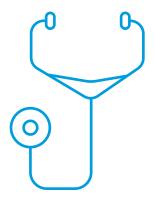
3. How many years have I needed PS?

4. Have I experienced any complications from PS?

5. Will it be possible to reduce my PS volume in the future?

6. Will it be possible to reduce the number of day(s) per week I'm infusing PS?





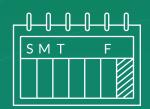
	7. How does GATTEX help me manage my SBS?
	8. What are the potential benefits of taking GATTEX?
	9. What are the possible risks and side effects of GATTEX?
	10. What types of tests and procedures will I need before starting GATTEX and while taking GATTEX?
	11. Will GATTEX affect the medications I'm currently taking?
ADDITIONAL QUESTIC	ONS FOR MY DOCTOR



What would a day off 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

Please remember that no two SBS patients are alike, so individual results vary.

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.

Important Safety Information (continued)

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,

nausea 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

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 (continued)

The most common side effects of GATTEX in adults include:

- stomach area (abdomen) pain or swelling
- nausea

- vomiting
- · 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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