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# Gattex<sup>®</sup>

## Teduglutide [rDNA origin] for Injection

### MENU

**Important Safety Information:** GATTEX may cause serious side effects including making abnormal cells grow faster, polyps in the colon (large intestine), blockage of the bowels (intestines), swelling (inflammation) or blockage of your gallbladder or pancreas, and fluid overload. Click [here](#) for additional Important Safety Information.

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## Why Choose GATTEX<sup>®</sup>?

CFAD Exhibit 1061



*Hypothetical patient portrayal*

***Learn more about how adults with Short Bowel Syndrome who needed additional nutrition or fluids from intravenous (IV) feeding (parenteral support) responded to once-daily GATTEX in clinical studies. GATTEX may help the remaining bowel absorb more. Remember, individual results may vary.***

**GATTEX helped patients reduce their weekly parenteral support\* after 6 months of treatment in a clinical trial**

- 63% of patients taking GATTEX responded to treatment compared with 30% of patients taking a placebo
- Response to treatment was defined as a reduction in parenteral support by 20% or more per week

**GATTEX helped reduce the average weekly volume and the number of day (s) on parenteral support after 6 months of treatment in a clinical trial**

- Patients taking GATTEX reduced their weekly parenteral support on average by 4.4 liters per week compared with 2.3 liters for patients on placebo
- Over 50% of patients who took GATTEX reduced their use of parenteral support by 1 day or more compared with 23% of patients taking a placebo

**GATTEX may cause serious side effects, including:**

- Making abnormal cells grow faster
- Polyps in the colon (large intestine)
- Blockage of the bowels (intestines)
- Swelling (inflammation) or blockage of your gallbladder or pancreas
- Fluid overload

**In a 2-year study, where patients knew they were taking once-daily GATTEX, the following results were seen:**

In the 30 patients who received a total of 2.5 years of treatment with GATTEX:

- 93% reduced their weekly parenteral support by 20% or more
- Average reduction of 7.55 liters per week of parenteral support compared to before starting GATTEX
- 70% of patients reduced their use of parenteral support by at least 1 day
- 10 patients were weaned off their parenteral support

In the 29 patients who received a total of 2 years of treatment with GATTEX:

- 55% reduced their weekly parenteral support by 20% or more
- Average reduction of 3.11 liters per week compared to before they started GATTEX
- 48% of patients reduced their use of parenteral support by at least 1 day
- 2 patients were weaned off their parenteral support

\* Parenteral support refers to food and fluids that are given to you through your veins rather than by mouth and includes both parenteral nutrition and/or intravenous (IV) fluids.

**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 colon (large intestine)***

Polyps are growths on the inside of the colon. Polyps were found in patients taking GATTEX in clinical studies. 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. Bowel blockage was reported in patients taking GATTEX in clinical studies. Tell your healthcare provider if you have any of these symptoms of a bowel 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 blockage is found, your healthcare provider may temporarily stop GATTEX.

***Swelling (inflammation) or blockage of your gallbladder or pancreas***

Swelling or blockage of the gallbladder or pancreas were reported in patients taking GATTEX in clinical studies. 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, change in your stools, nausea, vomiting, dark urine, or yellowing of your skin or the whites of eyes.

***Fluid overload***

Fluid overload and heart failure were reported in patients taking GATTEX in clinical studies. Too much fluid in your body may lead to heart failure, especially if you have heart problems. Your healthcare provider will check you for too much fluid in your body. 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 include:***

- stomach area (abdomen) pain or swelling
- skin reaction where the injection was given
- nausea
- headache
- cold or flulike symptoms
- vomiting

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 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
- Have any other medical condition
- 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 and your healthcare provider should decide if you will use GATTEX or breastfeed. You should not do both.

**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 you take while using GATTEX. Tell the healthcare provider who gives you GATTEX if you will be taking a new oral medicine.

**For additional safety information, click here for [Prescribing Information](http://www.shirecontent.com/PI/PDFs/Gattex_USA_ENG.pdf) ([http://www.shirecontent.com/PI/PDFs/Gattex\\_USA\\_ENG.pdf](http://www.shirecontent.com/PI/PDFs/Gattex_USA_ENG.pdf)) and [Medication Guide](http://www.shirecontent.com/MEDGUIDE/PDFs/MG_Gattex_USA_ENG.pdf) ([http://www.shirecontent.com/MEDGUIDE/PDFs/MG\\_Gattex\\_USA\\_ENG.pdf](http://www.shirecontent.com/MEDGUIDE/PDFs/MG_Gattex_USA_ENG.pdf)) and discuss with your doctor.**

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](http://www.fda.gov/medwatch) (<http://www.fda.gov/Safety/MedWatch/default.htm>) or call 1-800-FDA-1088. You can also call Shire at 1-855-5GATTEX (1-855-542-8839).

### ***What is GATTEX?***

**GATTEX is a prescription medicine used in adults with Short Bowel Syndrome (SBS) who need additional nutrition or fluids from intravenous (IV) feeding (parenteral support).**

(<http://www.shire.com>)



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