

LETTER FROM PHYSICIAN: MEDICAL TRAVEL NEEDS

Date: _____

To whom it may concern:

_____ is a patient under my care for the management of short bowel syndrome (SBS), a serious and chronic malabsorption disorder that 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. People with SBS are at risk for malnutrition, electrolyte disturbances, increased outputs, and dehydration.

As a part of their treatment plan, this patient must administer a daily injection of GATTEX® (teduglutide). Many people with SBS also require long-term parenteral support (PS), or intravenous (IV) feeding, to receive essential nutrients.

It is MEDICALLY NECESSARY for this patient to carry some or all of the following supplies:

- GATTEX kit
 - Vials of GATTEX
 - Prefilled syringes containing diluent (0.5 mL sterile water for injection, USP)
 - Plastic syringes with needles attached (1 mL, 27G x 1/2 inch)
 - Needles to be attached to the diluent syringes (23G x 1 1/2 inches)
 - Alcohol swab pads
- Portable pump with carrying case, batteries, power packs, charging apparatus, tubing, syringes, and needles
- Other medication:

- Alcohol, chlorhexidine, and/or povidone iodine preparations, such as wipes, pads, or swab sticks
- Catheter supplies: dressing change supplies, tape, gauze, transparent dressings, gloves, injection caps, and alcohol-based hand sanitizer
- PS solutions and IV fluid solutions (example: 0.45% NaCl, 0.9% NaCl, D5 0.45% NaCl, D5 0.9% NaCl, 5% dextrose in water), as needed
- Ice or ice packs
- Water, food, and/or electrolyte beverages

If you have any questions regarding this patient, please contact me at:

(Physician's signature)

(Practice name)

(Physician's name)

(Practice phone number)

For additional safety information, see full Prescribing Information and Medication Guide, and discuss any questions with your doctor.

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
- 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.

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

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 <http://www.fda.gov/medwatch> or call 1-800-FDA-1088.

For additional safety information, please see full Prescribing Information and Medication Guide, and discuss any questions with your doctor.



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

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Gattex®
(teduglutide) for injection