



Teduglutide (rDNA origin) for Injection



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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Learn about Sharps Disposal



NPS EX. 2134
CFAD v. NPS
IPR2015-01093

Shire is committed to simplifying the process of obtaining GATTEX with a multifaceted support program, OnePath®. Through OnePath, patients receive personal, dedicated service to help navigate obtaining and receiving treatment with GATTEX.

OnePath Case Managers notify GATTEX network specialty infusion pharmacies when GATTEX is prescribed for a patient. After GATTEX is delivered to the patient's home, a home visit is scheduled for a nurse to conduct injection training, provide education about proper needle and syringe disposal, review the Medication Guide and ensure that the patient is aware of available resources. Also, the nurse disseminates patient resources about GATTEX including:

- Prescribing Information
- Instructions for Use (IFU)
- Medication Guide
- Patient Demonstration Kit
- Administration Video
- Patient and Caregiver Counseling Guide
- How GATTEX Works Brochure

Patients are cautioned against the reuse of needles and syringes and they are provided education about disposal procedures. Patients are provided the following instructions:

- **Do not** reuse a syringe or needle.
- To help avoid needle-stick injuries, do not recap a needle.
- Put your needles and syringes in an FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and syringes in your household trash.**
- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
 - made of heavy-duty plastic
 - can be closed with a tight-fitting, puncture-resistant lid, without sharp items being able to come out
 - upright and stable during use
 - leak-resistant
 - properly labeled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be local or state laws about how to throw away syringes and needles. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal> (<http://www.fda.gov/safesharpsdisposal>).
- Do not dispose of your sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your sharps disposal container.
- Throw away the GATTEX vial into the container where you put the syringes and needles.

If you have any questions, talk to your healthcare provider or pharmacist.

Patients who have additional questions or would like to receive copies of the patient resources can contact OnePath at 1-866-888-0660.

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)

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.

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.

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



[use.aspx](#)) **Contact Us (/contact-us.aspx)**

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