

GATTEX[®] Patient and Caregiver Counseling Guide

GATTEX[®] (Teduglutide [rDNA origin]) for Injection is indicated for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

Healthcare providers: Please review this guide with your patient and/or your patient's caregiver.

Patients: Please read the enclosed Medication Guide in full and ask your doctor if you have any questions.



Understanding the Risks With 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.

Before you start using GATTEX, your healthcare provider will:

- Have your colon checked for polyps within 6 months before starting GATTEX
- 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.
- 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. 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.

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
- yellowing of your skin or the whites of eyes

Monitor Your Treatment With GATTEX

GATTEX may cause serious side effects, including:

- **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.
- See “Understanding the risks with GATTEX” on page 2 of this guide

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 flu-like symptoms
- Vomiting

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Please read the enclosed Medication Guide.



The GATTEX® Discussion

Before you use 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 and 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.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Remember:

- Tell your healthcare provider if you have any side effect that bothers you or that does not go away
- You may report side effects to the FDA at 1-800-FDA-1088
- You can also call the toll-free GATTEX Information Line at 1-855-5GATTEX (1-855-542-8839)

For more information about GATTEX, visit www.GATTEXREMS.com.

Please read the enclosed Medication Guide.

To learn more, visit www.GATTEXREMS.com.



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