

MEDICATION GUIDE

GATTEX® (Ga'-tex) (teduglutide [rDNA origin]) for injection

Read this Medication Guide carefully before you start taking GATTEX® and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical problems or treatment.

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 increase risk that abnormal cells could become cancer. If you get cancer of the bowel (intestines), liver, gall bladder, or pancreas while using GATTEX, your healthcare provider should stop GATTEX.
- If you get other types of cancers, you and your healthcare provide 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
- nausea
- vomiting

- chills
- fever
- change in your stools
- dark urine
- yellowing of your skin or the whites of eyes

These are not all the side effects of GATTEX. For more information, see **“What are the possible side effects of GATTEX?”**

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).

It is not known if GATTEX is safe or effective in children.

What should I tell my healthcare provider before using GATTEX?

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.

How should I use GATTEX?

- Use GATTEX exactly as your healthcare provider tells you to.
- GATTEX is given 1 time each day at the same time.
- Inject your dose of GATTEX under the skin (subcutaneous injection) in your stomach area (abdomen), upper legs (thighs), or upper arms. **Do not inject GATTEX into a vein or muscle.**
- Use a different injection site each time you use GATTEX.
- GATTEX comes as a powder for injection in a vial that is used only 1 time (single-use vial). The powder must be mixed with Sterile Water for Injection (a diluent) provided in a pre-filled syringe before you inject it.
- GATTEX must be injected within 3 hours after you mix it with the diluent.

- **If you miss a dose, take it as soon as you remember that day. Take your next dose the next day at the same time you take it every day.**
- **Do not take 2 doses on the same day.**
- **If you use more than 1 dose, call your healthcare provider right away.**
- **Read the Instructions for Use for detailed instructions for preparing and injecting a dose of GATTEX.**

What are the possible side effects of GATTEX?

GATTEX may cause serious side effects, including:

- See **“What is the most important information I should know about GATTEX?”**
- **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 include:

- stomach area (abdomen) pain or swelling
- skin reaction where the injection was given
- nausea
- headache
- cold or flu like symptoms
- vomiting
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Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of GATTEX.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store GATTEX?

- Store GATTEX powder at room temperature up to 25°C (77°F).
- Do not freeze GATTEX.
- Use the GATTEX powder by the expiration date on the “Use By” sticker on the kit. Use GATTEX within 3 hours after mixing it.
- Throw away any unused GATTEX that has been mixed, even if there is medicine left in the vial.
- Do not store any GATTEX you have mixed.

Keep GATTEX and all medicines out of the reach of children.

General information about the safe and effective use of GATTEX

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use GATTEX for a condition for which it was not prescribed. Do not give GATTEX to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information about GATTEX talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about GATTEX that is written for health professionals.

For more information go to www.GATTEX.com or call 1-855-542-8839.

What are the ingredients in GATTEX?

Active ingredient: teduglutide

Inactive ingredients: L-histidine, mannitol, monobasic sodium phosphate monohydrate, and dibasic sodium phosphate heptahydrate.

Sterile Water for Injection is provided as a diluent.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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