

GATTEX REMS: What You Need to Know About GATTEX[®] Treatment: A Patient & Caregiver Counseling Guide

Patients and Caregivers:

Your doctor or nurse will go over this Patient & Caregiver Counseling Guide with you. Make sure you ask any questions that you may have about GATTEX. Keep this guide for important safety information about the serious risks and reactions of GATTEX.

Healthcare Providers:

Review this Patient & Caregiver Counseling Guide with your patient or caregiver(s) each time and provide your patient with a copy to take home.

**Gattex**[®]
(teduglutide) for injection

What is GATTEX®?

GATTEX 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.

What Are the Most Serious Risks Related to GATTEX Treatment?

GATTEX can make abnormal cells that are already in your body grow faster.

There is a potential risk that abnormal cells could become cancer. If you, or the patient you care for, get cancer of the stomach, intestines, liver, gallbladder, or pancreas while using GATTEX, your doctor should stop GATTEX treatment. If you, or the patient you care for, get other types of cancers, you and your doctor should discuss the risks and benefits of using GATTEX.

GATTEX may cause polyps in the stomach and intestines.

Polyps are growths on the inside of the stomach and intestines.

BEFORE starting GATTEX, your doctor will:	AFTER starting GATTEX, your doctor will:
<ul style="list-style-type: none">✓ In adults: check your stomach and intestines for polyps within 6 months before starting GATTEX and remove all polyps.✓ In pediatric patients: check for blood in the stool within 6 months before starting GATTEX. <p>If there is blood found in the stool, your doctor should check your stomach and intestines for polyps and remove all polyps.</p>	<ul style="list-style-type: none">✓ In adults: check your stomach and intestines for new polyps at the end of 1 year of using GATTEX. If no polyp is found, your doctor should check you for polyps every 5 years or more often if needed.✓ In pediatric patients: check for blood in the stool annually. If there is blood found in the stool, your doctor should check your stomach and intestines for polyps. Your doctor should check your stomach and intestines at the end of 1 year of using GATTEX and every 5 years while using GATTEX.✓ In adults and pediatric patients: Remove any new polyps. If cancer is found in a polyp, you must stop GATTEX treatment.

GATTEX may prevent food, fluids, and gas from moving through your bowels (intestines) in a normal way. Tell your doctor if you, or the patient you care for, have any of these symptoms that could be a sign of blockage of the bowel:

- 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.

GATTEX can cause swelling (inflammation) or blockage of your gallbladder or pancreas.

Your doctor will do tests to check your gallbladder or pancreas within 6 months before starting GATTEX and at least every 6 months while you, or the patient you care for, are using GATTEX. Tell your doctor 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

What Can I Do to Help Lower the Risks of GATTEX?

Tell your doctor if you, or the patient you care for:

- Have cancer or a history of cancer
- Have or had Polyps anywhere in your stomach, 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 doctor 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. Talk to your healthcare provider about the best way to feed your baby while using GATTEX. Breastfeeding is not recommended during treatment with GATTEX.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using GATTEX with certain other medicines may cause side effects.

Where Can I Get More Information on GATTEX?

For more information about GATTEX REMS, visit GATTEXREMS.com. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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

A copy of the Medication Guide can be obtained by visiting www.GATTEXREMS.com or by calling 1-855-5GATTEX - (1-855-542-8839) to obtain a hard copy.



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