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

Reference ID: 4745364

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 bowel (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 colon (large intestine).
Polyps are growths on the inside of the colon.

BEFORE you start GATTEX, your doctor will:	**AFTER** you start GATTEX, your doctor will:
✔ In adults, check your colon for polyps within 6 months before starting GATTEX and remove all polyps. ✔ In children and adolescents, check for blood in the stool.	✔ Check your colon for new polyps at the end of 1 year of using GATTEX. If no polyp is found, your doctor should check you for polyps as needed and at least every 5 years. ✔ 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

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GATTEX can cause swelling (inflammation) or blockage of your gallbladder or pancreas. Your doctor will do tests to check your gallbladder and 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
- Had polyps anywhere in your bowel (intestines) or rectum
- Heart problems
- High blood pressure
- Problems with your gallbladder, pancreas, kidneys
- 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.
- Are taking medicines, 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 the 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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