



GATTEX RMP: What You need to Know About GATTEX Treatment: A Patient & Guide

**Gattex**[®]
(Teduglutide [rDNA origin]) 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 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:
<ul style="list-style-type: none">✓ 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.	<ul style="list-style-type: none">✓ 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

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 Are the Most Serious Risks Related to GATTEX Treatment?

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 or 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 GATTE.

- 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.

Contact Information and reporting of side effects

Reporting of side effects

Side effects can be reported to the Israeli Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” that appears on the homepage of the Ministry of Health’s website (www.health.gov.il) which links to a portal, or by the following link: <https://sideeffects.health.gov.il/> and by emailing the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com
Tel: 1-800-250-255

