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Gattex[®]

Teduglutide [rDNA origin] for Injection

MENU

Important Safety Information: GATTEX may cause serious side effects including making abnormal cells grow faster, polyps in the colon (large intestine), blockage of the bowels (intestines), swelling (inflammation) or blockage of your gallbladder or pancreas, and fluid overload. Click [here](#) for additional Important Safety Information.

[HOME \(/home.aspx\)](#) » [PATIENT SUPPORT \(/patient-support.aspx\)](#) » [PATIENT ASSISTANCE PROGRAM \(/patient-support/patient-assistance-program.aspx\)](#)

Patient Assistance Program

CFAD Exhibit 1074
CFAD v. NPS
IPB2015-00000



Hypothetical patient and doctor portrayal

Make the Connection With OnePath®

OnePath is a customized support program that provides assistance for people who are starting treatment with GATTEX®.

Starting a new treatment can be overwhelming. You may not know where to go for answers, whom to talk to, or even what to ask.

OnePath offers support that is personal, caring and confidential. You will be assigned a designated Case Manager—an experienced guide who will work with you to get started and help navigate the challenges you may encounter while on treatment.

To connect with a Case Manager, please call the OnePath Team at 1-866-888-0660.

Download the Start Form below, and bring it to your next Doctor's appointment. If your Doctor thinks that GATTEX is right for you, then you will complete this form together so that you can access the resources and support offered by OnePath.

DOWNLOAD THE START FORM >> [\(/assets/pdf/StartForm.pdf\)](/assets/pdf/StartForm.pdf)

Our Case Managers can help you manage challenges that can prevent you from accessing your therapy. Your Case Manager can help you with:

Insurance Access and Coverage Issues

Dedicated Case Managers will do a full insurance benefit exploration to help ensure you understand your coverage for GATTEX.

Co-Pay Assistance*

If you have commercial insurance but need assistance with out-of-pocket expenses, you may be eligible for one of our OnePath Co-Pay Assistance Programs. Your Case Manager can guide you through the process and help you follow up on your application.

Product Access Program

If you are uninsured or have insurance that does not cover GATTEX, you may be eligible for our OnePath Patient Assistance Program. Your Case Manager is committed to helping you explore all of the options available to give you access to the therapy your doctor has prescribed.

**Important Note: The OnePath Co-Pay Assistance Program (“the Program”) is not valid for prescriptions eligible to be reimbursed, in whole or in part, by Medicaid, Medicare (including Medicare Part D), or other federal or state programs (including any state prescription drug assistance programs). No claim for reimbursement of the out-of-pocket expense amount covered by the Program shall be submitted to any third-party payer, whether public or private. The Program cannot be used with any other rebate/coupon, free trial, or similar offer. Co-payment assistance under the Program is not transferable. The Program only applies in the United States and does not apply where prohibited by law, taxed, or restricted. Shire reserves the right to rescind, revoke, or amend the Program at any time without notice. Additional program restrictions may apply.*

If you have questions about GATTEX, we'll help you get answers. To reach a Case Manager, call 1-866-888-0660.

Important Safety Information

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 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. Polyps were found in patients taking GATTEX in clinical studies. Your healthcare provider will have your colon checked for polyps within 6 months before starting GATTEX and 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 and 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. Bowel blockage was reported in patients taking GATTEX in clinical studies. 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

Swelling or blockage of the gallbladder or pancreas were reported in patients taking GATTEX in clinical studies. 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, or yellowing of your skin or the whites of eyes.

Fluid overload

Fluid overload and heart failure were reported in patients taking GATTEX in clinical studies. Too much fluid in your body may lead to heart failure, especially if you have heart problems. Your healthcare provider will check you for too much fluid in your body. 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 flulike symptoms
- vomiting

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

What should I tell my healthcare provider before using 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 or 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.

For additional safety information, click here for [Prescribing Information](http://www.shirecontent.com/PI/PDFS/Gattex_USA_ENG.pdf) (http://www.shirecontent.com/PI/PDFS/Gattex_USA_ENG.pdf) and [Medication Guide](http://www.shirecontent.com/MEDGUIDE/PDFS/MG_Gattex_USA_ENG.pdf) (http://www.shirecontent.com/MEDGUIDE/PDFS/MG_Gattex_USA_ENG.pdf) and discuss with your doctor.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch (<http://www.fda.gov/Safety/MedWatch/default.htm>) or call 1-800-FDA-1088. You can also call Shire at 1-855-5GATTEX (1-855-542-8839).

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).

(<http://www.shire.com>)



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