LESS PS. MORE TIME DOING WHAT THEY LOVE.

Gattex® (teduglutide) for injection

For your patients ≥ 1 year of age with SHORT BOWEL SYNDROME (SBS) who are dependent on parenteral support (PS).[1]

SBS IS A SERIOUS AND CHRONIC MALABSORPTION DISORDER[2,3]

- SBS is the result of physical loss and functional deficiency of portions of the intestine, primarily due to surgical resection*†

*Patients with SBS require varying fluid/nutritional interventions based on individual needs.

†All patients who were included in the clinical trials described had previous bowel resections.

LEARN MORE ABOUT SBS →

TREATMENT GOALS FOR PATIENTS WITH SBS[4]

- Reduce or eliminate the need for PS and increase oral and/or enteral feeding
- Maintain adequate nutrition and hydration requirements
- Minimize disease- and PS-related complications
- Promote intestinal adaptation

LEARN MORE ABOUT TREATMENT GOALS →

IN CLINICAL TRIALS OF PATIENTS WITH SBS, GATTEX WAS PROVEN TO[1]:

Significantly reduce weekly PS **VOLUME** requirements

In a 6-month pivotal trial, adult patients treated with GATTEX reduced weekly PS volume by ≥20% (27/43) vs placebo (13/43) at Weeks 20 and 24; *P*=0.002, the primary endpoint.

Help patients achieve more **TIME** off of PS

In the same trial, adult patients achieved a reduction of ≥1 day off PS per week (21/39) vs placebo (9/39), an exploratory endpoint.

Help some patients achieve complete **FREEDOM** from PS

In a 24-month open-label extension, adult patients previously treated with GATTEX in the pivotal trial weaned off PS completely after 30 months of treatment (10/30)—the average duration was ~20 months.

In a 6-month pivotal trial, pediatric patients ≥1 year treated with GATTEX reduced weekly PS volume by ≥20% (18/26), the primary endpoint. They also achieved a reduction of ≥1 day off PS per week (10/26)—mean PS infusion time at baseline was 7 days/week and patients weaned off PS completely (3/26), secondary endpoints.

SEE RESULTS IN ADULTS →

SEE RESULTS IN PEDIATRICS ≥1 YEAR →

GLP-2

GATTEX IS THE FIRST AND ONLY FDA-APPROVED ANALOG OF NATURALLY OCCURRING GLP-2[1]

DISCOVER HOW GATTEX WORKS →

GATTEX HAS A DEMONSTRATED SAFETY PROFILE[1]

REVIEW SAFETY DATA →

IF YOU'RE READY TO START YOUR APPROPRIATE PATIENTS ON GATTEX, WE CAN HELP

GETTING STARTED →

- Please see the full Prescribing Information.
- Access the GATTEX REMS.

OFFER PATIENTS SUPPORT DURING THEIR TREATMENT JOURNEY

PATIENT SUPPORT RESOURCES →

DISCOVER THE GATTEX COMMUNITY ON FACEBOOK →

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Acceleration of Neoplastic growth

Colorectal polyps were identified during clinical trials. There is a risk for acceleration of neoplastic growth. In adults, within 6 months prior to starting treatment with GATTEX, colonoscopy of the entire colon with removal of polyps should be performed and follow-up colonoscopy (or alternate imaging) is recommended at the end of 1 year of GATTEX. Subsequent colonoscopies should be performed every 5 years or more often as needed.

In children and adolescents, perform fecal occult blood testing prior to initiating treatment with GATTEX. Colonoscopy/sigmoidoscopy is required if there is unexplained blood in the stool. Perform subsequent fecal occult blood testing annually in children and adolescents while they are receiving GATTEX. Colonoscopy/sigmoidoscopy is recommended for all children and adolescents after 1 year of treatment, every 5 years thereafter while on continuous treatment with GATTEX, and if they have new or unexplained gastrointestinal bleeding.

In case of intestinal malignancy (GI tract, hepatobiliary, pancreatic), discontinue GATTEX. The clinical decision to continue GATTEX in patients with non-gastrointestinal malignancy should be made based on benefit-risk considerations.

Intestinal obstruction

Intestinal obstruction has been reported in clinical trials and postmarketing. In patients who develop intestinal or stomal obstruction, GATTEX should be temporarily discontinued pending further clinical evaluation and management.

Biliary and pancreatic disease

Cholecystitis, cholangitis, cholelithiasis, and pancreatitis have been reported in clinical trials and postmarketing. Laboratory assessment (bilirubin, alkaline phosphatase, lipase, amylase) should be obtained within 6 months prior to starting GATTEX. Subsequent laboratory tests should be done every 6 months or more often as needed. If clinically meaningful changes are seen, further evaluation is recommended including imaging, and continued treatment with GATTEX should be reassessed.

Fluid imbalance and fluid overload

Fluid overload and congestive heart failure have been observed in clinical trials. If fluid overload occurs, especially in patients with underlying cardiovascular disease, parenteral support should be adjusted and GATTEX treatment reassessed. If significant cardiac deterioration develops while on GATTEX, continued GATTEX treatment should be reassessed. Discontinuation of treatment with GATTEX may also result in fluid and electrolyte imbalance. Fluid and electrolyte status should be monitored in patients who discontinue treatment with GATTEX.

Increased absorption of concomitant oral medication

In clinical trials, one patient receiving prazepam concomitantly with GATTEX experienced dramatic deterioration in mental status progressing to coma during first week of GATTEX therapy. Patients receiving concomitant oral drugs requiring titration or with a narrow therapeutic index should be monitored for adverse reactions due to potential increased absorption of the concomitant drug. The concomitant drug may require a reduction in dosage.

Adverse Reactions

The most common adverse reactions (≥ 10%) with GATTEX are abdominal pain, nausea, upper respiratory tract infection, abdominal distension, injection site reaction, vomiting, fluid overload, and hypersensitivity.

Use in Specific Populations

Breastfeeding is not recommended during treatment with GATTEX.

INDICATION

GATTEX® (teduglutide) for injection is indicated for the treatment of adults and pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

Please see full Prescribing Information.

If you are a Colorado prescriber, please see the Colorado WAC disclosure here.

References: 1. GATTEX (teduglutide) for injection [package insert]. Lexington, MA: Shire-NPS Pharmaceuticals, Inc. **2.** Jeppesen PB, JPEN. *J Parenter Enteral Nutr.* 2014;38(suppl 1):8S-13S. **3.** O'Keefe SJ, Buchman AL, Fishbein TM, et al. *Clin Gastroenterol Hepatol.* 2006;4(1):6-10. **4.** Kelly DG, Tappenden KA, Winkler MF. *J Parenter Enteral Nutr.* 2014;38(4):427-437.

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