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.

Important Safety Information
Warnings and Precautions
GATTEX has been associated with acceleration of neoplastic growth, intestinal obstruction, biliary and pancreatic disease, fluid imbalance and fluid overload, and increased absorption of concomitant oral medication.

Please click here for full Prescribing Information.
The action of endogenous GLP-2 plays a critical role in the absorption of nutrients in the intestine\(^1\)\(^-\)\(^5\)

In the distal intestine, L cells secrete GLP-2 in response to nutrients.\(^1\)

**Secretion of GLP-2 in the intestine\(^5\)**

**GLP-2 secretion:**
- Increases villus height and crypt depth\(^5\)\(^,\)\(^6\)
- Increases intestinal and portal blood flow\(^7\)\(^-\)\(^9\)
- Inhibits gastric acid secretion\(^7\)\(^-\)\(^9\)

The functions of GLP-2 facilitate the absorption of nutrients.\(^1\)\(^,\)\(^3\)\(^-\)\(^5\)

Native GLP-2 secretion may be impacted in patients with Short Bowel Syndrome (SBS).\(^8a\)

*SBS results from surgical resection, congenital defect, or disease-associated loss of absorption. The concomitant malabsorptive spectrum of SBS is wide, and patients with SBS are heterogeneous because of large variations in remnant bowel anatomy and function.\(^10\)*

**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.

Please click here for full Prescribing Information.
GATTEX® is the first and only FDA-approved analog of naturally occurring human GLP-2.

**Amino acid structural formula**

- 33 amino acid chain
- ~7-minute half-life

**Endogenous GLP-2**

- 33 amino acid chain
- The second-position alanine is replaced with glycine
- ~1.3-hour half-life in adult SBS patients

**In the intestines, GATTEX**: 

- Binds to the GLP-2 receptors
- Triggers the local release of multiple mediators, including insulin-like growth factor (IGF)-1, nitric oxide, and keratinocyte growth factor (KGF)

The ability of GATTEX to improve intestinal absorption was studied in 17 adult patients with SBS (N=2-3 per dose group) using daily doses of 0.03, 0.1, or 0.15 mg/kg (doses ranging from 0.6 to 3 times the recommended dose) in a 21-day, open-label, multicenter, dose-ranging study. All subcutaneous (abdomen) doses studied, except 0.03 mg/kg once daily, resulted in enhanced gastrointestinal fluid (wet weight) absorption of approximately 750-1000 mL/day, and increased villus height and crypt depth of the intestinal mucosa.

**Important Safety Information**

**Warnings and Precautions (continued)**

**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.

Please click here for full Prescribing Information.
More than twice as many adult patients on GATTEX® had a response to treatment compared with placebo in STEPS\(^b\)

- 63% (27/43) of patients had at least a 20% reduction in weekly parenteral support\(^c\) volume from baseline (immediately before randomization) to both Weeks 20 and 24, versus 30% (13/43) of patients taking placebo \((P=0.002)\) in the STEPS study\(^b\)

**Patients sustained their response to GATTEX® in STEPS\(^2\)**

- 93% (28/30) of patients who received GATTEX\(^\oplus\) both in STEPS and STEPS2 for a total of 30 months had at least a 20% reduction in weekly parenteral support volume from baseline
- Of the responders in STEPS who had completed 2 additional years of continuous treatment with GATTEX\(^\oplus\), 96% (22/23) sustained their response to GATTEX\(^\oplus\)

\(^a\)STEPS, a 6-month, randomized, double-blind, placebo-controlled, multicenter clinical trial of adult SBS patients dependent on parenteral support (PS) \(\geq 3\) times/week for \(\geq 12\) months, had, as a primary efficacy endpoint, a \(\geq 20\)% reduction in weekly PS volume from baseline to Weeks 20 and 24.

\(^b\)Parenteral support refers to parenteral nutrition and/or essential fluids.

\(^c\)Patients from STEPS (GATTEX\(^\oplus\), n=37; placebo, n=39) enrolled in STEPS2, a 24-month, open-label extension study. All patients (N=88), including 12 who were never in STEPS, received GATTEX\(^\oplus\) in STEPS2. Results shown here use 30-month data only from patients who received GATTEX\(^\oplus\) in STEPS and STEPS2. Response was defined as a \(\geq 20\)% or greater reduction of weekly parenteral support.

**Important Safety Information**

**Warnings and Precautions (continued)**

**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 (\(\geq 10\)% 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.

For more information, contact Takeda at 1-855-5GATTEX (542-8839), or visit www.gattex.com.

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**References:**


GATTEX® was proven to enhance the absorptive capacity of the remaining bowel.\(^7\)