Gattex®
(teduglutide) for injection

Dosing Guidelines and Diagnosis Code Reference

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

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.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Diagnosis Codes[1]

ICD-10-CM Codes for Short Bowel Syndrome

K90.82	Short Bowel Syndrome
K90.821	Short bowel syndrome with colon in continuity
K90.822	Short bowel syndrome without colon in continuity
K90.829	Short bowel syndrome, unspecified

How Supplied[2]

GATTEX® for injection is supplied as 5 mg of teduglutide as a white, lyophilized powder for reconstitution in a sterile, single-dose glass vial with 0.5 mL Sterile Water for Injection in a single-dose prefilled syringe. The product to be dispensed is either a 1 vial kit or a 30 vial kit. **Use of the GATTEX 5 mg kit is not recommended in pediatric patients weighing less than 10 kg.**

Recommended Dosage[2]

The recommended dosage of GATTEX for both adults and pediatric patients is 0.05 mg/kg once daily by subcutaneous injection.

Dosage Adjustment for Renal Impairment[2]

The **recommended dosage in adult and pediatric patients** with moderate and severe renal impairment and end-stage renal disease (estimated glomerular filtration rate [eGFR] less than 60 mL/min/1.73 m^2 is **0.025 mg/kg once daily**

References: 1. Centers for Medicare & Medicaid Services. 2024 ICD-10-CM. Accessed August 30, 2023. https://www.cms.gov/medicare/icd-10/2024-icd-10-cm **2.** GATTEX (teduglutide) for injection [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Acceleration of Neoplastic growth (cont'd)

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.

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Dosing Calculations (Recommended Dose)[2]

PATIENT WEIGHT: _____ kg

DAILY DOSE: _____ kg (PATIENT WEIGHT) X 0.05 mg / 1 kg = _____ mg/day

LIQUID DOSE: _____ mg (DAILY DOSE) X 0.5 mL / 5 mg = _____ mL/day

The following table provides GATTEX® dosing calculations for patients weighing 22-200 lb

Patient Weight (lb)	Patient Weight (kg)	Liquid Dose (mL)
22 lb	10 kg*	0.05 mL
25 lb	11.4 kg	0.06 mL
30 lb	13.6 kg	0.07 mL
35 lb	15.9 kg	0.08 mL
40 lb	18.2 kg	0.09 mL
45 lb	20.5 kg	0.1 mL
50 lb	22.7 kg	0.11 mL
55 lb	25 kg	0.13 mL
60 lb	27.3 kg	0.14 mL
65 lb	29.5 kg	0.15 mL
70 lb	31.8 kg	0.16 mL
75 lb	34.1 kg	0.17 mL
80 lb	36.4 kg	0.18 mL
85 lb	38.6 kg	0.19 mL
90 lb	40.9 kg	0.2 mL
95 lb	43.2 kg	0.22 mL
100 lb	45.5 kg	0.23 mL
105 lb	47.7 kg	0.24 mL
110 lb	50 kg	0.25 mL

Patient Weight (lb)	Patient Weight (kg)	Liquid Dose (mL)
115 lb	52.3 kg	0.26 mL
120 lb	54.5 kg	0.27 mL
125 lb	56.8 kg	0.28 mL
130 lb	59.1 kg	0.3 mL
135 lb	61.4 kg	0.31 mL
140 lb	63.6 kg	0.32 mL
145 lb	65.9 kg	0.33 mL
150 lb	68.2 kg	0.34 mL
155 lb	70.5 kg	0.35 mL
160 lb	72.7 kg	0.36 mL
165 lb	75 kg	0.38 mL†
170 lb	77.3 kg	0.39 mL
175 lb	79.5 kg	0.4 mL
180 lb	81.8 kg	0.41 mL
185 lb	84.1 kg	0.42 mL
190 lb	86.4 kg	0.43 mL
195 lb	88.6 kg	0.44 mL
200 lb	90.9 kg	0.45 mL

*Use of the GATTEX 5 mg kit is not recommended in pediatric patients weighing less than 10 kg.[2]
†A maximum of 0.38 mL of the reconstituted solution, containing 3.8 mg of GATTEX, can be withdrawn from a single-dose vial.[2]

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Acceleration of Neoplastic growth (cont'd)

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

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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.

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Takeda

Gattex® (teduglutide) for injection