**IN CLINICAL TRIALS OF PATIENTS WITH SBS, GATTEX WAS PROVEN TO:**

- **Significantly reduce** final volume requirements
- **Help patients achieve more time** of PS-free during 1-year follow-up
- **Help some patients achieve complete freedom** from PS
- **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**

**INTERNATIONAL FACILITY AND INDICATION**

**GATTEX® (teduglutide) for injection** 

**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 (PS).

**USE IN SPECIFIC POPULATIONS**

- **Intestinal Obstruction**: Colonoscopy/sigmoidoscopy is recommended for all children and adolescents after 1 year of treatment, every 5 years or more often as needed. If clinically meaningful changes are seen, further evaluation is recommended including (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.

- **Colorectal Polyps**: Colorectal polyps were identified during clinical trials. There is a risk for acceleration of neoplastic growth. In adults, it is 6-months prior to starting treatment with GATTEX. Colonoscopy of the entire colon is recommended in patients with a history of colorectal cancer. If polyposis is identified, colonoscopy and/or sigmoidoscopy is recommended at least annually. In children and adolescents, perform fecal occult blood testing prior to initiating treatment with GATTEX. See full Prescribing Information for more information.

**ADVERSE REACTIONS**

- **Injection Site Reactions**: Microabscesses have been reported with GATTEX injection. The incidence of these events was equal across the treatment groups in clinical trials. Colonoscopy/sigmoidoscopy is recommended at the end of 1 year of GATTEX. Subsequent colonoscopies should be performed every 5 years or more often as needed.

- **Fluid Imbalance and Fluid Overload**: Fluid assessments and fluid balance have been observed in clinical trials. If fluid overload occurs, especially in patients with underlying cardiovascular disease, permit support should be adjusted and GATTEX treatment discontinued. If significant cardiac deterioration develops while on GATTEX, continue GATTEX treatment discontinued. Discontinuation of treatment with GATTEX may be necessary if hypovolemia, hyponatremia, or electrolyte disturbances remain uncorrected.

- **Increased Risk of Hypertension and Hypotension**: In clinical trials, some patients receiving GATTEX experienced hypotension and hypertension leading to discontinuation of treatment in 20% of patients. Monitor patients for blood pressure changes while on GATTEX and adjust treatment if necessary. If significant hypotension occurs requiring discontinuation of treatment, adjust treatment and continue GATTEX treatment.

**INTERACTIONS**

- **Parenteral Drug Administration**: If other drugs are administered concomitantly, perform both a thorough history and physical examination and a drug interaction assessment. If fluid overload occurs, especially in patients with underlying cardiovascular disease, permit support should be adjusted and GATTEX treatment discontinued. If significant cardiac deterioration develops while on GATTEX, continue GATTEX treatment discontinued. Discontinuation of treatment with GATTEX may be necessary if hypovolemia, hyponatremia, or electrolyte disturbances remain uncorrected.

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