

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Zorbtive (somatropin) is a human growth hormone (hGH) produced by recombinant DNA technology. Zorbtive is approved for use in the treatment of short bowel syndrome (SBS) in patients who are on a specialized diet. SBS is a rare, serious and potentially life-threatening condition that follows extensive surgical removal of portions of the small intestine as a treatment for acute or chronic disorders of the intestine. Removal of a large portion of the bowel results in impaired absorption of nutrients. Currently the standard treatment for SBS involves careful management of dietary intake and hydration, or where appropriate, a process referred to as parenteral nutrition in which patients are fed through an intravenous tube. On rare occasions, surgical transplant of the intestine may also be performed for this condition (1).

Intestinal mucosa contains receptors for growth hormone and for insulin-like growth factor-1 (IGF-1), which is known to mediate many of the cellular actions of growth hormone. Thus, the actions of growth hormone on the gut may be direct or mediated via the local or systemic production of IGF-1. In human clinical studies, the administration of growth hormone has been shown to enhance the transmucosal transport of water, electrolytes, and nutrients (1).

The potential for misuse or abuse of Zorbtive is high since it is the same medication used for growth hormone deficiencies. Growth hormones misuse is prevalent with athletes and body builders and among those seeking its purported anti-aging and weight loss effects (2).

Regulatory Status

FDA-approved indication: Zorbtive is a recombinant human growth hormone indicated for the treatment of short bowel Syndrome in patients receiving specialized nutritional support (1).

Specialized nutritional support may consist of a high carbohydrate, low-fat diet, adjusted for individual patient requirements and preferences. Nutritional supplements may be added according to the discretion of the treating physician. Zorbtive therapy should be used in conjunction with optimal management of Short Bowel Syndrome. Optimal management of Short Bowel Syndrome may include dietary adjustments, enteral feedings, parenteral nutrition, and fluid and micronutrient supplements, as needed (1).



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ZORBTIVE (somatropin)

Patients should be informed that allergic reactions are possible and that prompt medical attention should be sought if an allergic reaction occurs. Zorbtive is contraindicated in patients with acute critical illness, active malignancy, and diabetic retinopathy (1).

Recombinant human growth hormone (r-hGH) has been associated with acute pancreatitis. The use of somatropin has been associated with cases of new onset impaired glucose intolerance. New onset type 2 diabetes mellitus and exacerbation of preexisting diabetes mellitus have been reported in patients receiving somatropin. Some patients developed diabetic ketoacidosis and diabetic coma. In some patients, these conditions improved when somatropin was discontinued, while in others the glucose intolerance persisted. Some patients required initiation or adjustment of anti-diabetic treatment while on somatropin. Patients with other risk factors for glucose intolerance should be monitored closely during Zorbtive therapy (1).

Safety and effectiveness of Zorbtive in pediatric patients less than 18 years of age have not been established (1).

Summary

Zorbtive (somatropin) is a human growth hormone (hGH) produced by recombinant DNA technology. Intestinal mucosa contains receptors for growth hormone and for insulin-like growth factor-1 (IGF-1), which is known to mediate many of the cellular actions of growth hormone. Zorbtive is FDA approved for the treatment of short bowel syndrome in patients receiving specialized nutritional support (1). The potential for misuse or abuse of Zorbtive is high since it is the same medication used for growth hormone deficiencies. Growth hormone misuse is prevalent with athletes and body builders and among those seeking its purported anti-aging and weight loss effects (2). Safety and effectiveness of Zorbtive in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Zorbtive while maintaining optimal therapeutic outcomes.

References



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1. Zorbtive [package insert]. Rockland, MA. EMD Serono, Inc. September 2019.
2. Growth Hormone: Use and Abuse; Journal of Clinical Endocrinology and Metabolism - Volume 94, Issue 6 (June 2009).