

TEV-TROPIN[®] [somatropin (rDNA origin) for injection] is indicated only for the treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone (GH).

Important Safety Information

TEV-TROPIN[®] stimulates linear growth in children lacking endogenous GH. Treatment of growth hormone-deficient (GHD) children with TEV-TROPIN[®] produces growth rate and IGF-1 levels similar to those seen after treatment with hGH of pituitary origin.

Unless patients with Prader-Willi Syndrome (PWS) also have a diagnosis of GHD, TEV-TROPIN[®] is not indicated for treatment of pediatric patients who have growth failure due to genetically confirmed PWS. Because of reported fatalities, patients with PWS who are severely obese, have severe respiratory impairment, respiratory infections, or sleep apnea should interrupt use of GH.

Patients should be observed for evidence of glucose intolerance, hypopituitarism, malignant transformation of skin lesions, hypothyroidism, slipped capital femoral epiphysis, and intracranial hypertension. Funduscopic examination of patients is recommended at the initiation and periodically during the course of GH treatment. TEV-TROPIN[®] should not be initiated in patients with acute critical illness as a complication of open heart surgery, abdominal surgery, multiple accidental trauma, or those with acute respiratory failure. TEV-TROPIN[®] should not be used in patients with evidence of an active malignancy, progressive or recurrent underlying intracranial tumor, active proliferative or severe nonproliferative diabetic retinopathy, or closed epiphysis.

When somatropin is administered subcutaneously at the same site over a long period of time, tissue atrophy may result. This can be avoided by rotating the injection site.

Because somatropin increases growth rate, patients with a history of scoliosis who are treated with somatropin should be monitored for progression of scoliosis.

Somatropin may alter the clearance of drugs metabolized by the CP450 enzyme system and careful monitoring is advisable.

Benzyl alcohol associated with toxicity in newborns is contained in the diluent supplied with TEV-TROPIN[®]. Treatment of patients with coexisting ACTH deficiency should have glucocorticoid replacement dose adjusted to avoid inhibition of growth.

In studies of growth hormone-deficient children, headaches occurred infrequently. Injection-site reactions (eg, pain, bruise) occurred in 8 of the 164 treated patients.