

TEV-TROPIN[®] [somatotropin (rDNA origin) for injection] is indicated for the treatment of children who have growth failure due to growth hormone deficiency (GHD).

Important Safety Information

Growth hormone may be used in children with confirmed Prader-Willi Syndrome only when diagnosed with GHD. Children who are severely overweight, have breathing problems while awake or asleep, and have lung infections should stop use of growth hormone and consult a physician. This may occur more in boys.

Changes in eyesight, headaches, nausea, and vomiting may occur. Frequent eye examinations should be done before and during treatment. Patients should be observed for elevated blood glucose, underactive thyroid, underactive pituitary, skin cancers, development of a limp, or complaint of hip or knee pain. Patients with rapid onset critical illness as a result of open heart or abdominal surgery, multiple accidental trauma, or rapid onset respiratory failure should not be started on TEV-TROPIN[®]. Patients with injury or active cancer in the brain, eye problems related to diabetes, or bones that have stopped growing should not receive recombinant growth hormone.

When TEV-TROPIN[®] is administered at the same site over a long period of time, damage to the tissue may result. This can be avoided by rotating the injection site.

Because TEV-TROPIN[®] increases growth rate, patients with a history of curvature of the spine (scoliosis) should be monitored.

TEV-TROPIN[®] may interfere with other drugs removed from the body by the liver and careful monitoring is advisable.

The liquid provided to mix TEV-TROPIN[®] should not be used in newborns because of associated toxicity. Doses of reconstituted TEV-TROPIN[®] greater than 1 mL are not recommended. Consult your child's physician for doses greater than 1 mL. Do not exceed the dose recommended by your child's physician.

In studies of GHD children, headaches occurred infrequently. Injection-site reactions, for instance pain or bruising, occurred in 8 of the 164 treated patients.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.