

The following plan is posted in compliance with California SB 486.

Teva Biologics and Specialty Products Safe Needle Collection and Disposal Plan

Teva Biologics and Specialty Products, a division of Teva Pharmaceuticals USA, Inc, the marketer of TEV-TROPIN[®] [somatropin (rDNA origin) for injection], a therapy indicated for Growth Hormone Deficiency, is committed to ensuring that GHD patients have access to the information they need to keep themselves and their households safe and in compliance with local and state sharps disposal laws.

Teva educates patients regarding the importance of proper needle and syringe disposal through the dissemination of patient communication materials, as well as through Growth Solutions[®], the patient support program for TEV-TROPIN[®], which is available to children with GHD and their caregivers.

Growth Solutions[®], through its more than 50 nurses nationwide, provides a variety of services, including 24-hour call center support for anyone with questions about GHD, as well as injection support for people taking TEV-TROPIN[®] therapy. Growth Solutions[®] nurses discuss proper needle and syringe disposal with patients over the phone and in person when training the patient on how to properly reconstitute and administer TEV-TROPIN[®]. In addition, Growth Solutions[®] nurses discuss proper needle and syringe disposal as a key component of patient injection training.

Information about proper sharps disposal is available through a number of key TEV-TROPIN[®] communications, including:

- TEV-TROPIN[®] Prescribing Information
- TEV-TROPIN[®] Patient Instruction Brochure (English/Spanish)
- TEV-TROPIN[®] Patient Instruction DVD
- TEV-TROPIN.com
- TEV-TROPIN[®] Patient Prescribing Information

In these TEV-TROPIN[®] communications, patients are cautioned against the reuse of needles or syringes and educated about safe disposal procedures. Patients are instructed to:

- Check with their local health department, doctor's office, or pharmacist for guidance and follow local regulations for disposal
- Dispose of used syringes into a hard-walled plastic container or disposable biohazard sharps container immediately after injection
- Use each syringe with TEV-TROPIN[®] for only 1 injection
- Always keep the waste container in an area of your home that is out of the reach of children and pets
- Use a puncture-resistant container for disposal of used needles and syringes

Patients interested in learning more about proper needle and syringe disposal may contact Growth Solutions[®] toll-free, day or night, at 1-866-838-8767.

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.

[Please see additional important information for TEV-TROPIN[®].](#)

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