



January 2011

IMPORTANT SAFETY INFORMATION REGARDING ALCOHOL PREP PADS MANUFACTURED BY TRIAD CO-PACKAGED WITH GENENTECH PRODUCTS

(Fuzeon® (enfuvirtide); Boniva® Injection (ibandronate sodium); Pegasys® (pegylated interferon alfa-2a); TNKase® (tenecteplase); Nutropin AQ® (somatropin (rDNA origin)) Pen 10 Kit; Nutropin AQ® (somatropin (rDNA origin)) Pen 20 Kit)

Dear Healthcare Professional:

Recall of Triad Group Alcohol Prep Products Due to Potential Microbial Contamination

Genentech, Inc., a member of the Roche Group, has learned of a voluntary product recall in the United States involving all lots of alcohol prep pads, alcohol swabs and alcohol swabsticks manufactured by the Triad Group and marketed under various brand names. The Triad Group alcohol prep pads are co-packaged with the following Genentech products: Fuzeon®; Boniva® Injection; Pegasys®; TNKase®; Nutropin AQ® Pen 10 Kit; and Nutropin AQ® Pen 20 Kit. The Genentech medicines have **not** been affected in any way. In the interest of patient safety, Genentech wants to ensure that you and your patients are aware of this recall of only the alcohol prep products by the Triad Group.

This recall by the Triad Group has been initiated due to concerns about potential bacterial contamination of the alcohol prep products with *Bacillus cereus*. This recall involves alcohol prep products marked as sterile, as well as non-sterile products. As indicated on the FDA website in regard to this recall: "Use of contaminated alcohol prep pads, alcohol swabs and alcohol swabsticks could lead to life-threatening infections, especially in at-risk populations, including immune suppressed and surgical patients." It is important to note that the packaged Genentech products and components (with the exception of the alcohol prep pads) have **not** been contaminated and may continue to be used in accordance with the package insert.

Genentech recommends that you immediately discontinue use of the alcohol prep pads packaged with these medicines. **Inform your patients of this recall and request that they immediately discontinue using the co-packaged alcohol prep pads.** The prep pads should be disposed of in the trash. When administering an injection of any of these Genentech products, healthcare providers and patients should use an alternative alcohol prep product that is not involved with this recall or alternatively use a sterile gauze pad in conjunction with isopropyl alcohol for disinfecting the injection site prior to administration.



Genentech is in discussion with the FDA and is currently assessing alternatives to address the situation.

Additional information on this recall by the Triad Group can be found on the FDA's website: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm239319.htm>.

If you or your patients have any further questions or require additional information, please contact the Genentech Resource Center at 1-877-GENENTECH.

You are encouraged to report side effects associated with the use of these products to Genentech and the FDA's MedWatch Safety Information and Adverse Event Reporting Program, which can be found at www.fda.gov/medwatch or call 1-800-FDA-1088.

For the Fuzeon indication, full prescribing information, and important safety information, please visit www.fuzeon.com.

For the Boniva indication, full prescribing information, and important safety information, please visit www.boniva.com.

For the Pegasys indication, full prescribing information, and important safety information including Boxed WARNING and Medication Guide, please visit www.pegasys.com.

For the TNKase indication, full prescribing information, and important safety information, please visit www.tnkase.com.

For the Nutropin AQ indication, full prescribing information, and important safety information, please visit www.nutropin.com.

Sincerely,

Hal Barron, MD
Executive Vice President
Head, Global Development
Chief Medical Officer