

**IMPORTANT
PRESCRIBING
INFORMATION**

August 2011

Subject: Sterile Water for Injection vials packaged with FUZEON® (enfuvirtide) kits

Dear Healthcare Professionals and Patients:

In February 2011, Genentech changed its supplier for sterile water for injection (called “sterile water”) vials for FUZEON Convenience Kits distributed in the US. Recently, we have received complaints from patients regarding their inability to remove the necessary amount of sterile water from the new vials.

Genentech, in consultation with the FDA, has confirmed that the sterile water vials currently supplied in the kit are appropriate for patient use and that **patients may continue to use their FUZEON Convenience Kits as prescribed and as described in the Injection Instructions that are included with each kit.** Genentech, in consultation with the FDA, is working with the sterile water vial supplier to modify the existing amount of sterile water to ensure that all patients are able to easily extract the necessary amount from the vial provided. FUZEON should only be mixed and dissolved using the sterile water vials supplied in the FUZEON Convenience Kit.

Your sterile water vials now come from a different supplier. If you are not able to draw up 1.1 mL from the vial, use the amount you are able to draw up. It should not change how you prepare and inject your FUZEON. Please see the Dosage and Administration section of the Prescribing Information. If you have any questions, please call 1-877-438-9366.

Patients should continue to follow the Injection Instructions included with the FUZEON Convenience Kit for preparing and injecting FUZEON. Patients should talk to their healthcare provider about any new or continuing side effects. Patients with questions or needing additional information should speak with their healthcare provider. Additionally, patients may call **1-877-4FUZEON (1-877-438-9366)** or visit www.fuzeon.com.

As always, healthcare professionals are encouraged to report side effects associated with the use of FUZEON to Genentech at 1-888-835-2555. Alternatively, such information may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program, either online at www.fda.gov/medwatch, by telephone (1-800-FDA-1088), by facsimile (1-800-FDA-0178), or by mail using the MedWatch Form FDA 3500 (FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville MD 20852-9787).

Sincerely,



Hal Barron, M.D.
Chief Medical Officer
Genentech, Inc.

Enclosure

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