

**IMPORTANT  
SAFETY  
INFORMATION**

October 2012

**Subject: Important Safety Information – Infusion Set Included in the BONIVA® (ibandronate sodium) Injection Kit (NDC 0004-0191-09)**

Dear Healthcare Professional,

BONIVA Injection has been packaged as a kit (NDC 0004-0191-09) containing one prefilled syringe of BONIVA Injection and the TERUMO® SurShield™ Safety Winged (25 gauge “butterfly” needle) Infusion Set (Terumo Infusion Set) supplied by Terumo Medical Products Hangzhou Co., Ltd. (Terumo). Genentech would like to inform you of important safety information concerning the co-packaged Terumo Infusion Set.

The Food and Drug Administration (FDA) recently issued a Warning Letter and subsequently an Import Alert to Terumo describing good manufacturing practice (cGMP) compliance deficiencies concerning its infusion set. These deficiencies were identified by the agency during a site inspection. Given these deficiencies, Genentech has determined that there is a risk that the needle shield (a safety feature of the infusion set) may not perform as intended, and that this in turn could result in a needle stick injury to a healthcare provider administering the BONIVA Injection. For further information concerning the cGMP compliance deficiencies, please refer to the 2012 Warning Letter which is available on the FDA website at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm308058.htm>

The Import Alert is also available on the FDA website at [http://www.accessdata.fda.gov/cms\\_ia/importalert\\_241.html](http://www.accessdata.fda.gov/cms_ia/importalert_241.html)

In the interest of helping to ensure healthcare professional safety, and until further notice, Genentech is no longer including the Terumo Infusion Set in the BONIVA Injection kit. Please note that these cGMP compliance deficiencies do **NOT** impact the quality, safety or efficacy of the BONIVA Injection *drug product*.

**Recommended Action**

If you have BONIVA Injection kits in stock that *do* contain an infusion set, please do not use the co-packaged infusion set. The co-packaged infusion set should be discarded according to the policies and procedures of your facility, as well as Federal and Local regulations for “Sharps Disposal.” You may also have BONIVA Injection kits that do not contain an infusion set; these are identifiable by the label affixed to the outside of the kit which reads “ATTENTION: INFUSION SET NOT INCLUDED.” In either circumstance, please use as an alternative, a standard needle of 23 gauge or smaller bore with

a safety feature to administer the BONIVA Injection. Until we identify a new needle to be co-packaged with BONIVA, we recommend ensuring proper needle to syringe connectivity prior to infusion. An infusion line does not need to be opened.

### **Important Information about BONIVA Injection Dosage and Administration**

BONIVA Injection is a nitrogen-containing bisphosphonate that is indicated for the treatment of osteoporosis in postmenopausal women.

In postmenopausal women with osteoporosis, BONIVA increases bone mineral density (BMD) and reduces the incidence of vertebral fractures.

The safety and effectiveness of BONIVA for the treatment of osteoporosis are based on clinical data of one year duration. The optimal duration of use has not been determined. All patients should have the need for continued therapy re-evaluated on a periodic basis.

The recommended dose of BONIVA Injection for the treatment of postmenopausal osteoporosis is 3 mg every 3 months administered intravenously over a period of 15 to 30 seconds.

BONIVA Injection must be administered by a healthcare professional.

BONIVA Injection must only be administered intravenously over a period of 15 to 30 seconds. Care must be taken not to administer BONIVA Injection intra-arterially or paravenously as this could lead to tissue damage.

Do not administer BONIVA Injection by any other route of administration. The safety and efficacy of BONIVA Injection following non-intravenous routes of administration have not been established.

Please see the BONIVA Full Prescribing Information enclosed with this letter or visit [www.gene.com](http://www.gene.com) for Important Safety Information. If you have any questions or require additional information regarding the use of BONIVA, please contact our Medical Communications Group at 1-800-821-8590 from 5:30 AM to 4:00 PM Pacific Time, Monday through Friday.

As always, healthcare professionals are encouraged to report side effects associated with the use of BONIVA 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](http://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, MD  
Executive Vice President  
Head, Global Development  
Chief Medical Officer