



Lilly Announces Important Action Regarding Recall of Alcohol Prep Pads Made by Triad Group Included in Forteo Starter Kits

This Recall Does Not Affect or Involve Forteo Delivery Device

INDIANAPOLIS, March 17, 2011 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that patients should not use the alcohol prep pads made by the Triad Group that are contained in the black starter kits for Forteo® [teriparatide (rDNA origin) injection] in the United States. The Triad Group is recalling the alcohol prep pads due to potential contamination with the bacteria, *Bacillus cereus*, which could result in life threatening infections, especially in at-risk populations, including immune suppressed and surgical patients. **It is important to note that this recall does not affect or involve the Forteo Delivery Device.** The starter kits did not contain the Forteo Delivery Device.

Some Forteo starter kits distributed by Eli Lilly and Company between March 2008 and June 2009 may have contained Triad Group alcohol prep pads. The Triad alcohol prep pads should **not** be used. The Forteo starter kits that contained the Triad alcohol prep pads were black bags and were discontinued in June 2009. The Forteo starter kits have been updated since June 2009. The bags are now blue, do not include Triad alcohol prep pads, nor any other alcohol prep pad.

Lilly has requested that physicians and their staff examine their inventory of Forteo starter kits and remove and appropriately discard the Triad Group alcohol prep pads in the black bags. Lilly has also requested that physicians inform any patients who may have received Forteo starter kits containing Triad Group alcohol prep pads to discontinue use of the pads.

Further information about this recall can be found at <http://www.fda.gov/Safety/Recalls/ucm239219.htm>. For questions pertaining to the recall, consumers may contact Triad Group at 262-538-2900.

Adverse reactions or quality problems experienced with the use of the Triad alcohol prep pads may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm
- Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

About Forteo

Forteo is used in both men and postmenopausal women with osteoporosis who are at high risk for having fractures. FORTEO can be used by people who have had a fracture related to osteoporosis, or who have several risk factors for fracture, or who cannot use other osteoporosis treatments.

Forteo is used in both men and women with osteoporosis due to use of glucocorticoid medicines, such as prednisone, for several months, who are at high risk for having broken bones (fractures). These include men and women with either a history of broken bones, who have several risk factors for fracture, or who cannot use other osteoporosis treatments.

Important Safety Information about FORTEO

WARNING: POTENTIAL RISK OF OSTEOSARCOMA

During the drug testing process, the medicine in FORTEO caused some rats to develop a bone cancer called osteosarcoma. In people, osteosarcoma is a serious but rare cancer. Osteosarcoma has been reported rarely in people who took FORTEO. It is not known if people who take FORTEO have a higher chance of getting osteosarcoma. Before you take FORTEO, you should tell your healthcare provider if you have Paget's disease of bone, are a child or young adult whose bones are still growing, or have had radiation therapy.

Who should not take FORTEO?

You should not take FORTEO for more than 2 years over your lifetime.

Do not use FORTEO if you are allergic to any of the ingredients in FORTEO. Serious allergic reactions have been reported.

Talk to your healthcare provider before taking FORTEO

Before you take FORTEO, you should tell your healthcare provider if you have a bone disease other than osteoporosis, have cancer in your bones, have trouble injecting yourself and do not have someone who can help you, have or have had kidney stones, have or have had too much calcium in your blood, take medications that contain digoxin (Digoxin, Lanoxicaps, Lanoxin), or have any other medical conditions.

You should also tell your healthcare provider, before you take FORTEO, if you are pregnant or thinking about becoming pregnant. It is not known if FORTEO will harm your unborn baby. If you are breastfeeding or plan to breastfeed, it is not known if FORTEO passes into your breast milk. You and your healthcare provider should decide if you will take FORTEO or breastfeed. You should not do both.

What are the possible side effects of FORTEO?

FORTEO can cause serious side effects including a decrease in blood pressure when you change positions. Some people feel dizzy, get a fast heartbeat, or feel faint right after the first few doses. This usually happens within 4 hours of taking FORTEO and goes away within a few hours. For the first few doses, take your injections of FORTEO in a place where you can sit or lie down right away if you get these symptoms. If your symptoms get worse or do not go away, stop taking FORTEO and call your healthcare provider. FORTEO may also cause increased calcium in your blood. Tell your healthcare provider if you have nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood.

Common side effects of FORTEO include nausea, joint aches, pain, leg cramps, and injection site reactions such as redness, swelling, pain, itching, a few drops of blood, and bruising. These are not all the possible side effects of FORTEO.

Additional safety information about FORTEO

There is a voluntary patient registry for people who take FORTEO. The purpose of the registry is to collect information about the possible risk of osteosarcoma in people who take FORTEO. For information about how to sign up for this patient registry, call 1-866-382-6813 or go to www.forteoregistry.rti.org.

The FORTEO Delivery Device has enough medicine for 28 days. It is set to give a 20-microgram dose of medicine each day. Before you try to inject FORTEO yourself, a healthcare provider should teach you how to use the FORTEO Delivery Device to give your injection the right way. Inject FORTEO one time each day in your thigh or abdomen (lower stomach area). Do not inject all the medicine in the FORTEO delivery device at any one time. Do not transfer the medicine from the FORTEO delivery device to a syringe. This can result in taking the wrong dose of FORTEO. If you take more FORTEO than prescribed, call your healthcare provider. If you take too much FORTEO, you may have nausea, vomiting, weakness, or dizziness.

Keep your FORTEO Delivery Device in the refrigerator between 36 degrees to 46 degrees F (2 degrees to 8 degrees C). Do not freeze the FORTEO Delivery Device. Do not use FORTEO if it has been frozen. Do not use FORTEO after the expiration date printed on the delivery device and packaging. Throw away the FORTEO Delivery Device after 28 days even if it has medicine in it (see the User Manual).

For more information about FORTEO, please see the full prescribing information, including boxed warning (<http://pi.lilly.com/us/forteop-i.pdf>) and Med Guide (<http://pi.lilly.com/us/forteop-medguide.pdf>). You may also learn more about FORTEO at www.Forteo.com.

About Eli Lilly and Company

Eli Lilly and Company, a leading innovation-driven company, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers -- through medicines and information -- for some of the world's most urgent medical needs. Information about Lilly is available at www.lilly.com.

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(Logo: <http://photos.prnewswire.com/prnh/20031219/LLYLOGO>)

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