



California Dialysis Council

1904 Naomi Place • Prescott, AZ 86303 • Phone: 928-717-1156 • Fax: 928-441-3857



NEWS UPDATE



FDA NEWS RELEASE

For Immediate Release: June 13, 2009

Media Inquiries: Judy Leon 301-796-4624 judy.leon@fda.hhs. Karen Riley, 301-796-4674, karen.riley@fda.hhs.gov

The U.S. Food and Drug Administration has learned that some vials of the long-acting insulin Levemir made by Novo Nordisk Inc. have reappeared and are being sold in the U.S. market. Three lots or a total of 129,000 this product were stolen in all. These stolen insulin vials may not have been stored and handled properly and may be dangerous for patients to use.

The FDA has received one report of a patient who suffered an adverse event due to poor control of glucose levels after using a vial from one of three lots.

The agency is advising patients who use Levemir insulin to:

1. Check your personal supply of insulin to determine if you have Levemir insulin from one of the following lots: XZF0036, XZF0037, and XZF00 Patients can locate the lot number on the side of the box of insulin and also on the side of the vial.
2. Do not use your Levemir insulin if it is from one of these lots. Replace it with a vial of Levemir insulin from another lot. If you must switch to another brand of insulin for any reason, first contact your healthcare provider as another insulin product may require adjustments in dosing.
3. Always visually inspect your insulin before using it. Levemir is a clear and colorless solution.
4. Contact the Novo Nordisk Customer Care Center at 800-727-6500 for what to do with vials from these lots or if you have any other questions.

For more information: Novo Nordisk news release
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm166359.htm>