U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Drug Safety Communications

FDA requires label warnings to prohibit sharing of multi-dose diabetes pen devices among patients

Safety Announcement

[2-25-2015] In an effort to reduce the serious risk of infection spread through sharing of multi-dose diabetes pen devices intended for single patient use only, the U.S. Food and Drug Administration (FDA) is requiring additional label warnings prohibiting sharing of these injectable medicines. Insulin pens and pens for other injectable diabetes medicines should never be shared among patients, even if the needle is changed. Sharing pens can result in the spread of serious infections from one patient to another. To promote safe use, we are requiring that pens and packaging containing multiple doses of insulin and other injectable diabetes medicines display a warning label stating "For single patient use only."

Insulin and other injectable diabetes medicines are used to help lower or regulate blood sugar, which, when uncontrolled, can increase the risk for serious complications, including blindness, nerve and kidney damage, and heart disease. Injectable diabetes medicines can come in pen-shaped devices with either a reservoir or cartridge containing multiple doses of medicine (see list of medicines in Table 1 below). Each pen is designed to be safe for just one patient to use multiple times with a new, fresh needle for each injection. Pens must never be used for more than one patient because blood may be present in the pen after use. Sharing pens can lead to transmission of infections such as the human immunodeficiency virus (HIV) and hepatitis viruses.

Since 2008, we have learned of thousands of patients possibly exposed to infections that are transmitted through blood from the sharing of multi-dose pen devices for insulin and other injectable diabetes medicines (see Data Summary).[1-4] No confirmed cases of actual infection transmission have been reported, but sources of infection are often difficult to identify and may go unreported. In response to the reports of potential exposure, FDA and other organizations have issued multiple safety alerts, including a 2009 FDA Health Care Professional Sheet, and launched campaigns warning against the sharing of insulin pens.

The "For single patient use only" warning will appear on the labels affixed to the pens and on the pen cartons. Additional warnings against sharing pens will also be added to the prescribing information and to the patient Medication Guides, Patient Package Inserts, and Instructions for Use.

We urge health care professionals and patients to report medication errors or side effects involving diabetes medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Table 1. List of diabetes medicines with multi-dose pen devices

Brand name	**Generic name**
Apidra	insulin glulisine
Humalog	insulin lispro
Humalog Mix 50/50	50% insulin lispro protamine and 50% insulin lispro
Humalog Mix 75/25	75% insulin lispro protamine and 25% insulin lispro
Humulin N	human insulin isophane
Humulin R	regular insulin human
Humulin 70/30	70% human insulin isophane and 30% human insulin
Novolin N	human insulin isosphane
Novolog	insulin aspart
Novolog Mix 50/50	50% insulin aspart protamine and 50% insulin aspart
Novolog Mix 70/30	70% insulin aspart protamine and 30% insulin aspart
Lantus	insulin glargine
Levemir	insulin detemir
Symlin	pramlintide acetate
Victoza	liraglutide
Byetta	exenatide

Facts about diabetes medicines contained in pen devices

- Pen devices provide an alternative to a vial and syringe for injecting diabetes medicines.
- Numberous diabetes medicines have multi-dose pen devices. See Table 1 in the Safety Announcement section for a list of these medicines.
    - Apidra, Humalog, Humalog Mix 50/50, Humalog Mix 75/25, Humulin N, Humulin R, Humulin 70/30, Novolin N, Novolog, Novolog Mix 50/50, Novolog Mix 70/30, Lantus, and Levemir are insulin products used to lower blood sugar in patients with type 1 or type 2 diabetes.
    - Symlin is an amylin analog used to treat patients with type 1 or type 2 diabetes when a mealtime insulin dose has not controlled blood sugar well enough.
    - Victoza and Byetta are glucagon-like peptide-1 (GLP-1) receptor agonists used to improve blood sugar control in adults with type 2 diabetes, when used with a diet and exercise program.

- Additional information about diabetes and treatments for diabetes can be found at the following websites:
    - MedlinePlus: Diabetes
    - National Diabetes Information Clearinghouse: Treatments for Diabetes

Additional Information for Patients

- Never share your diabetes pen device with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.
- Read the Medication Guide, Patient Package Insert, and/or Instructions for Use that come with your diabetes pen prescriptions.
- Talk to your health care professional if you have any questions or concerns about how to properly use diabetes pens.
- Additional information about diabetes and treatments for diabetes can be found at the following websites:
    - MedlinePlus: Diabetes
    - National Diabetes Information Clearinghouse: Treatments for Diabetes
- Report medication errors or side effects from diabetes medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Additional Information for Health Care Professionals and Hospitals

- Pen devices for insulins and other diabetes drugs must never be shared among patients, even if the needle is changed. Sharing poses a risk for transmission of bloodborne pathogens, including human immunodeficiency virus (HIV) and the hepatitis viruses.
- To minimize medication errors in hospitals and other health care facilities, pens should be clearly labeled with each patient's name or other identifying information. Ensure the identifying patient information does not obstruct the dosing window or other product information such as the product name, strength, and the warning statement "For single patient use only."
- Verify the pen with the name of the patient and other patient identifiers to ensure the correct pen is used on the correct patient.
- Hospitals and other health care facilities should review their policies and educate their staff members regarding the safe use of diabetes pens.
- Counsel patients to never share their diabetes pens with another person.
- Report medication errors or adverse events involving diabetes drugs to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Data Summary

In March 2008, the Institute of Safe Medication Practices (ISMP) first alerted health care facilities that an individual patient's insulin pen may have been used on another patient.[1]

Since that time, FDA has learned that thousands of patients have possibly been exposed to bloodborne pathogens through the sharing of multi-dose insulin pens intended for use by single patients. Pen devices for insulins and other diabetes drugs are not designed for use by more than one patient.

In January 2009, a U.S. Army facility announced that 2,114 patients were potentially exposed to bloodborne pathogens when insulin pens intended for single patient use were used on more than one patient.[2] In response to the reports of potential exposure, FDA and other organizations issued safety alerts targeting health care facilities, patients, and health care professionals. In 2009, FDA and ISMP issued safety alerts that insulin pens are not designed for use by more than one patient.[5, 6] Then, in August 2011, the Dean Clinic in Wisconsin notified 2,345 patients of potential exposure to bloodborne pathogens when pens and needle stick devices were shared among patients.[3] In 2012, the Centers for Disease Control and Prevention launched the One and Only campaign to try to eliminate unsafe medical injections, and the Centers for Medicare & Medicaid Services notified its state and regional offices to survey health care facilities for the sharing of insulin pens.[7-9] In January 2013, the Veterans Health Administration notified 716 patients of potential exposure through the sharing of these devices.[4]

Multiple factors may have contributed to pens intended for single patients being used for more than one patient. These factors include lack of awareness of the risks associated with pen sharing, inconsistencies in training and/or lack of training on the proper use of these devices, time constraints, lack of understanding about the difference between multi-dose vials and multi-dose insulin pens, missing medications, and the lack of appropriate label warnings.

References

1. Institute of Safe Medication Practices. Acute Care ISMP Medication Safety Alert: Cross contamination with insulin pens. http://www.ismp.org/newsletters/acutecare/articles/20080327_1.asp. Published March 27, 2008. Accessed January 23, 2015.

2. Hakre S, Upshaw-Combs DR, Sanders-Buell EE, Scoville SL, Kuper JD, Jagodzinski LL, et al. An investigation of bloodborne pathogen transmission due to multipatient sharing of insulin pens. Mil Med 2012;177:930-8.

3. Wisconsin Office of Rural Health. Important Patient Safety Notification. http://worh.dreamhosters.com/state-news/important-patient-safety-notification. Published August 29, 2011. Accessed January 23, 2015.

4. Department of Veterans Affairs, Office of Inspector General, Office of Healthcare Inspections. Healthcare Inspection: Inappropriate Use of Insulin Pens at the VA Western New York Healthcare System in Buffalo, New York. http://www.va.gov/oig/pubs/VAOIG-13-01320-200.pdf. Published May 9, 2013. Accessed January 23, 2015.

5. Food and Drug Administration. Information for Healthcare Professionals: Risk of Transmission of Blood-borne Pathogens from Shared Use of Insulin Pens. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm133352.htm. Published March 19, 2009. Accessed February 3, 2015.

6. Institute of Safe Medication Practices. Acute Care ISMP Medication Safety Alert: Reuse of insulin pen for multiple patients risks transmission of bloodborne disease. http://www.ismp.org/newsletters/acutecare/articles/20090212-2.asp. Published February 12, 2009. Accessed February 3, 2015.

7. Centers for Disease Control and Prevention. Insulin Pen Safety – One Insulin Pen, One Person. http://www.oneandonlycampaign.org/content/insulin-pen-safety. Published 2012. Accessed February 3, 2015.

8. Centers for Disease Control and Prevention. CDC Clinical Reminder: Insulin Pens Must Never Be Used for More than One Person. http://www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html. Published January 4, 2012. Accessed February 3, 2015.

9. Centers for Medicare & Medicaid Services. Use of Insulin Pens in Health Care Facilities. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-30.pdf. Published May 18, 2012. Accessed February 3, 2015.