



تعميم اداري رقم (88) لسنة 2015

السادة الأفاضل /مدراء المناطق الطبية
المحترمين
السادة الأفاضل /مدراء المستشفيات الحكومية و الخاصة
المحترمين
السادة الأفاضل /مدراء الصيدليات الخاصة
المحرمين

الموضوع : إضافة تحذير على الأقلام التي تحتوي على جرعات متعددة من أدوية السكري

Label warnings to prohibit sharing of multi-dose diabetes pen devices among patients

نود أن نلفت انتباهكم الى أن هيئة الغذاء والدواء الأمريكية قد أصدرت تحذيرا بشأن المنتجات المذكورة أعلاه، حيث انه لا يجوز مشاركة أقلام الإنسولين وغيرها من أدوية السكري بين المرضى، حتى إذا تم تغيير الإبرة الموجودة مع القلم، وذلك لأنه قد يتسبب ذلك في انتشار انواع من العدوى الخطيرة من مريض إلى آخر.

وعليه توصي هيئة الغذاء والدواء الأمريكية ووزارة الصحة الشركات المنتجة بإضافة تحذير على الملصق الخارجي و الداخلي و النشرة الداخلية لمنتجاتهم من الأقلام و العبوات التي تحتوي على جرعات متعددة من الأنسولين وغيرها من أدوية السكري عن طريق الحقن، التحذير التالي " لاستخدام مريض واحد فقط "

ولمزيد من المعلومات عن هذا التحذير يرجى الاطلاع على الموقع:

http://www.fda.gov/Drugs/DrugSafety/ucm435271.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

علما بأن المنتجات المسجلة في إدارة الدواء بوزارة الصحة من المنتجات المذكورة أعلاه هي:

اسم المنتج	الوكيل المعتمد	الشركة المصنعة
Apidra Solostar Apidra 100U/ml (Optiset)	Pharmatrade	SANOFI-AVENTIS DEUTSCHLANDGmbH
Humalog 100U/ml kwikPen	Pharmatrade	LILLY FRANCE
Humalog Mix 50 kwikPen(PFS)		
Humalog Mix 25 kwikPen100U/ml		



Humulin N Pen 100U/ml	Pharmatrade	LILLY FRANCE SA
Humulin 70/30 Pen 100U/ml		
Byetta	Pharmatrade	BRISTOL-MYERS SQUIBB/ASTRAZENECA EEIG
Lantus Solostar Lantus 100U/ml (Optiset)	Pharmatrade	SANOFI-AVENTIS DEUTSCHLANDGmbH
Mixtard Penfill	City Pharmacy Co	NOVO NORDISK A/S
Insulatard® Penfill®		
Novomix Penfill		
Levemir		
Victoza		

وفي حال حدوث أي أعراض جانبية يرجى ملئ الإستمارة الخاصة بالآثار الجانبية للدواء ADR والمتوفرة على البريد الإلكتروني <http://www.cpd-pharma.ae> أو الإتصال على العناوين التالية: هاتف: 6117642 - 02 أو 6117421 الإلكتروني - 02 أو فاكس 6313742 - 02 أو البريد الإلكتروني pv@moh.gov.ae

و تفضلوا بقبول فائق الاحترام و التقدير.

د. أمين حسين الأميري

وكيل الوزارة المساعد لسياسة الصحة العامة والتراخيص

صدر بديوان عام الوزارة/ابوظبي بتاريخ: 2015/3/19
نسخة لـ:

- معالني / وزير الصحة
- سعادة / وكيل وزارة الصحة
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- سعادة / المدير التنفيذي لمدينة دبي الطبية
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- سعادة / مدير إدارة التمكين والإمتثال الصحي
- سعادة / مديرة إدارة الدواء

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Ants

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

[2-25-2015]

Safety Announcement

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.
- Numerous 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](#)

More Info 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.

More Info 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

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[Drug Safety Communication](#) (PDF - 57KB)

Contact FDA

For More Info

855-543-DRUG (3784)

and press 1

druginfo@fda.hhs.gov

Report a Serious Problem to MedWatch

Complete and submit the report [Online](#).

[Download form](#) or call 1-800-332-1088 to

request a reporting form, then complete

and return to the address on the

pre-addressed form, or submit by fax to

1-800-FDA-0178.