

October 15, 2020

COM-2020-082

## DRUG SAFETY NOTIFICATION



**DATE: October 13, 2020**

**DRUG NAME: Insulin Pen**

**DRUG INDICATION: Diabetes**

**SAFETY TOPIC: Insulin pen  
packaging and dispensing**

### Dear provider of pharmaceutical services,

PharmPix is committed to our member's health and wellness. The clinical team wants to communicate you with the latest up-to-date information on drug safety. We notify you that the U.S. Food and Drug Administration (FDA) clarifies the reasons for the revision to labeling insulin pens to a single patient in the original sealed carton. Those are increased risk of dispensing errors (wrong-drug and wrong-dose errors) that may result in hyperglycemia or hypoglycemia, incorrect use, missed dose, and complaints of possible tampering. The incorrect use of the insulin may be attributed to dispensing the product without instructions developed by the manufacturer.

### Recommendations for healthcare professionals:

- Dispense insulin pen to a single patient in the original sealed carton.
- If multiple insulin products are dispensed (short and long-acting formulations), advise the patient about the differences in the packaging (e.g., color, font size, name), use, and administration.

Report adverse events or side effects at [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) by any of the following ways:

- Complete and submit the [MedWatch Online Voluntary Reporting Form](#) online.
- [Download](#) FDA Form 3500 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.

Additional information can be found at [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) and [FDA's Drug Safety and Availability portal](#).

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. Also, know that you can access our recent communications at our providers' portal: <https://www.pharmpix.com/providers/>.

Regards,

PharmPix Clinical Department

Reference:

- FDA advises health care professionals and patients about insulin pen packaging and dispensing. U.S. Food and Drug Administration. (2020). Retrieved on October 15, 2020 from: [https://www.fda.gov/drugs/drug-safety-and-availability/fda-advises-health-care-professionals-and-patients-about-insulin-pen-packaging-and-dispensing?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/drugs/drug-safety-and-availability/fda-advises-health-care-professionals-and-patients-about-insulin-pen-packaging-and-dispensing?utm_medium=email&utm_source=govdelivery)