# Hospira Issues A Voluntary Nationwide Recall For Two Lots of Naloxone Hydrochloride Injection, USP, in the Carpuject™ Syringe System Due To The Potential Presence of Particulate Matter.

Monday, June 04, 2018 - 01:37pm

**FOR IMMEDIATE RELEASE**-LAKE FOREST, IL., June 4, 2018 - Hospira, Inc., a Pfizer company, is voluntarily recalling lots 72680LL and 76510LL of **Naloxone Hydrochloride Injection, USP, 0.4 mg/mL, 1 mL in 2.5 mL, Carpuject Single-use cartridge syringe system** (NDC 0409-1782-69), to the hospital/institution level due to the potential presence of embedded and loose particulate matter on the syringe plunger.

In the event that impacted product is administered to a patient, the patient has a low likelihood of experiencing adverse events ranging from local irritation, allergic reactions, phlebitis, end-organ granuloma, tissue ischemia, pulmonary emboli, pulmonary dysfunction, pulmonary infarction, and toxicity. The risk is reduced by the possibility of detection, as the labeling contains a clear statement directing visual inspection of the product for particulate matter and discoloration prior to administration. To date, Hospira, Inc. has not received reports of any adverse events associated with this issue for these lots.

Naloxone Hydrochloride, an opioid antagonist, is indicated for the complete or partial reversal of opioid depression. It is also indicated for the diagnosis of known or suspected

opioid overdosage, and as an adjunctive agent for the management of septic shock. It is available as a sterile solution for intravenous (IV), intramuscular (IM), and subcutaneous (SC) administration. Naloxone is supplied in a Carpuject- single-use cartridge with a 1 mL fill for use with the Carpuject syringe system.

The NDC, Lot Number, Expiration Date, Strength and Configuration details for Naloxone Hydrochloride Carpuject Injection is indicated below. Product lots were distributed nationwide to wholesalers/distributors/hospitals in the United States, Puerto Rico, and Guam from February 2017 to February 2018.

NDC Lot Number Expiration Date Strength Configuration/Count
0409-1782-03 (Single Unit)

0409-1782-69 (Box/Carton)

72680LL 1DEC2018 0.4 mg/mL, 1 mL in 2.5 mL 10 - 1 mL Single Use Carpuject™ (Sterile Cartridge Unit with Luer Lock) per box/carton; 100 boxes/cartons per case (1000)
76510LL 1APR2019 0.4 mg/mL, 1 mL in 2.5 mL
Hospira, Inc., places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process. Hospira, Inc. has notified wholesalers/ distributors/hospitals to arrange for return of any recalled product.

Distributors or retailers with an existing inventory of the lots, which are being recalled, should stop use and distribution and quarantine immediately. Inform Healthcare Professionals in your organization of this recall. If you have further distributed the recalled product, to the wholesale or retail level, please notify any accounts or additional locations which may have received the recalled product from you. For additional assistance, call Stericycle at 1-800-805-3093 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

Healthcare Professionals with questions regarding this recall can contact Pfizer using the below information.

**Contact Contact Information Areas of Support** Pfizer Medical Information 1-800-438-1985, option 3 (8am to 7pm ET Monday through Friday) Medical inquiries Pfizer Safety 1-800-438-1985, option 1 (24 hours a day 7 days per week) To report adverse events or product complaints

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by

regular mail or by fax.

Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm 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.

This recall is being executed with the knowledge of the U.S. Food and Drug Administration.

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Media: Kim Bencker (610)-329-1340 kim.bencker@pfizer.com