



FDA Issues Naloxone Recall

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 overdose, 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.

More information can be found on the U.S. Food and Drug Administration website, [here](#).

NDC	Number	Date	Strength	Configuration/Count
0409-1782-03 (Single Unit)	72680LL	1DEC2018	0.4 mg/mL 1 mL in 2.5mL	10-1 mL Single Use Carpuject&trad; (Sterile Cartridge Unit with Luer Lock) per box/carton; 100 boxes/cartons per case (1000)
0409-1782-69 (Box/Carton)	76510LL	1APR2019	0.4 mg/mL, 1 ml in 2.5 mL	
