firstscript

Clinical Bulletin

June 8, 2018

Subject: Drug Recall of Two Lots of Naloxone

Hospira, Inc., a Pfizer company, is voluntarily recalling two lots of Naloxone Hydrochloride Injections from hospitals and institutions due to the potential presence of embedded and loose particulate matter on the syringe plunger[1]. This recall does **not** affect other self-administered naloxone products Evzio® auto-injector or Narcan® Nasal Spray.

"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."[1]

The following lots are affected by this recall:

NDC	Lot Number	Lot Expiration Date	Strength	Configuration/Count
00409-1782-03 (Single Unit)	72680LL	12/1/2018	0.4 mg/mL, 1 mL in 2.5mL	10-1 mL Single Use Carpuject™; (Sterile Cartridge Unit with Luer Lock) per box/carton; 100 boxes/cartons per case (1000)
00409-1782-69 (Box/Carton)	76510LL	4/1/2019	0.4 mg/mL, 1 mL in 2.5mL	

Impact:
If administered to an injured worker, there is 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[1].

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

Reporting Adverse Reactions:
Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

There is very little impact to First Script clients from this recall. For more information, please contact your Account Manager or Account Pharmacist.

[1] https://www.fda.gov/Safety/Recalls/ucm609668.htm?utm_campaign=Hospira%20Issues%20a%20Voluntary%20Nationwide%20Recall%20for%20Two%20Lots%20of%20Naloxone%20Hydrochloride%20Injection&utm_medium=email&utm_source=Eloqua

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