

The United States: Hospira Carpuject Pre-filled Cartridges - Drug Alert: Products May Contain More Than the Intended Fill Volume

FDA is alerting healthcare providers of a potential safety risk in some Carpuject pre-filled cartridges manufactured by Hospira, Inc. The pre-filled cartridges containing the products listed below may be overfilled by at least twice the expected amount, resulting in potential overdose.

FDA is advising healthcare providers to follow the instructions provided with the medication and visually inspect and confirm that the Carpuject pre-filled cartridge contains the labeled fill volume before dispensing and again before administering to patients. If a Carpuject pre-filled cartridge contains a greater volume of medication than described by the label, healthcare providers should not use the Carpuject pre-filled cartridge and should return it to Hospira.

Hospira, Inc. has informed the FDA of the occurrence of overfilled Carpuject pre-filled cartridges containing morphine and hydromorphone following complaints received from healthcare providers. Subsequent inspection of retained product by Hospira found additional overfilled Carpuject pre-filled cartridges.

The manufacturing problem thought to be responsible for this overfilling has resulted in the risk for overfilled Carpuject pre-filled cartridges for as many as 280 lots of 15 different Carpuject pre-filled cartridge products. However, according to the firm's investigation, the number of Carpuject pre-filled cartridges in a lot that may contain an overfill appears to be low.

Because pharmacists and other healthcare providers can visually identify the presence of an overfilled Carpuject pre-filled cartridge, FDA is recommending that these steps be taken at this time rather than a product recall, because a recall of the affected products listed above would result in an immediate shortage. FDA is still evaluating whether additional steps are necessary.

Pre-filled cartridges for the following Hospira Carpuject products should be visually inspected for the possibility of overfill:

Product Name	Strength	Presentation
Demerol (meperidine HCl) Injection, USP	25 mg/mL	1 mL in 2.5 mL Carpuject, Luer Lock
	50 mg/mL	1 mL in 2.5 mL Carpuject, Luer Lock
	75 mg/mL	1 mL in 2.5 mL Carpuject, Luer Lock
Diazepam Injection, USP	5 mg/mL	2 mL in 2.5 mL Carpuject, Luer Lock
Fentanyl Citrate Injection, USP	100 mcg Fentanyl/2 mL	2 mL in 2.5 mL Carpuject, Luer Lock
Heparin Lock Flush Solution, USP	10 USP heparin units/mL	1 mL in 2.5 mL Carpuject, Luer Lock
	100 USP heparin units/mL	1 mL in 2.5 mL Carpuject, Luer Lock
	100 USP heparin units/mL	3 mL in 5 mL Carpuject, Luer Lock
	10 USP heparin units/mL	5 mL in 5 mL Carpuject, Luer Lock
	100 USP heparin units/mL	5 mL in 5 mL Carpuject, Luer Lock
Heparin Sodium Injection, USP	5,000 USP heparin units/mL	1 mL in 2.5 mL Carpuject, Luer Lock
	10,000 USP heparin units/mL	0.5 mL in 2.5 mL Carpuject, Luer Lock
HYDROMORPHONE HCl Injection, USP	1 mg/mL	1 mL in 2.5 mL Carpuject, Luer Lock
	2 mg/mL	1 mL in 2.5 mL Carpuject, Luer Lock
	4 mg/mL	1 mL in 2.5 mL Carpuject, Luer Lock
Ketorolac Tromethamine Injection, USP	30 mg/mL	1 mL in 2.5 mL Carpuject, Luer Lock

Labetalol Hydrochloride Injection, USP	20 mg/4 mL (5 mg/mL)	4 mL in 5 mL Carpuject, Luer Lock
Lorazepam Injection, USP	2 mg/mL	1 mL in 2.5 mL Carpuject, Luer Lock
Metoprolol Tartrate Injection, USP	1 mg/mL	5 mL in 5 mL Carpuject, Luer Lock
Midazolam Injection, USP	2 mg/2 mL (1 mg/mL), Preservative-Free	2 mL in 2.5 mL Cartridge, iSecure Version 2
	2 mg/2 mL (1 mg/mL), Preservative-Free	2 mL in 2.5 mL Carpuject, Luer Lock
Morphine Sulfate Injection, USP	4 mg/mL	1 mL in 2.5 mL Carpuject, Luer Lock
	8 mg/mL	1 mL in 2.5 mL Carpuject, Luer Lock
	10 mg/mL	1 mL in 2.5 mL Carpuject, Luer Lock
	15 mg/mL	1 mL in 2.5 mL Carpuject, Luer Lock
Naloxone Hydrochloride Injection, USP	0.4 mg/mL	1 mL in 2.5 mL Carpuject, Luer Lock
Ondansetron Injection, USP	2 mg/mL	2 mL in 2.5 mL Cartridge, iSecure Version 2
Sodium Chloride Injection, USP	0.90%	2 mL in 2.5 mL Carpuject, Luer Lock
	0.90%	3 mL in 5 mL Carpuject, Luer Lock
	0.90%	5 mL in 5 mL Carpuject, Luer Lock

Please refer to the following website in FDA for details:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm305236.htm>

<http://www.fda.gov/Drugs/DrugSafety/ucm304902.htm>

In Hong Kong, the above products are not registered pharmaceutical products. News regarding the Hospira Carpuject pre-filled cartridges containing Morphine sulfate injection 4mg/ml and Hydromorphone hydrochloride injection 1mg/ml has been released by the FDA and were posted on the website of Drug Office on 18 April and 14 May 2012.

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