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

U.S. Food & Drug Administration

AUDIENCE: Risk Manager, Health Professional

ISSUE: 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 in the Drug Alert may be overfilled by at least twice the expected amount, resulting in potential overdose.

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 would result in an immediate shortage.

BACKGROUND: 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.

RECOMMENDATION: 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] 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

[05/23/2012 – Drug Alert [3] - FDA]
[05/23/2012 - Dispensing Pharmacists and Health Care Provider Instructions [4] - FDA]

Related MedWatch Alert:

[05/14/2012 - Hydromorphone Hydrochloride Injection Recall [5]]

SOURCE [6]

Source URL (retrieved on *07/11/2014 - 5:44am*):
http://www.mdtmag.com/news/2012/05/hospira-carpuject-pre-filled-cartridges-drug-alert-products-may-contain-more-intended-fill-volume

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Drugs/DrugSafety/ucm304902.htm
[4] http://www.fda.gov/Drugs/DrugSafety/ucm304907.htm
[5] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm304044.htm
[6] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm305236.htm