



**U.S. Food and Drug Administration**

Protecting and Promoting *Your Health*

## Compounded Drugs Stored in Becton-Dickinson (BD) 3 ml and 5 ml Syringes: FDA Warning - Do Not Use

[Posted 08/18/2015]

**AUDIENCE:** Pharmacy, Compounding, Nursing, Risk Manager

**ISSUE:** FDA is alerting health care professionals not to administer to patients compounded or repackaged drugs that have been stored in 3 milliliter (ml) and 5ml syringes manufactured by Becton-Dickinson (BD) unless there is no suitable alternative available. Preliminary information indicates that drugs stored in these syringes may lose potency over a period of time due to a possible interaction with the rubber stopper in the syringe. If you have been using products packaged in these syringes, be aware that using a substitute product may require a dosage adjustment in case the patient has been receiving a subpotent product, or adverse consequences could occur.

BD's 10ml, 20ml and 30ml syringes may also contain the same rubber stopper. The company is alerting their customers not to use these syringes as a closed container system for compounded and repackaged drugs.

**BACKGROUND:** FDA has cleared these syringes as medical devices for general purpose fluid aspiration and injection only. These syringes were not cleared for use as a closed container storage system for drug products, and the suitability of these syringes for that purpose has not been established. This issue may extend to other general use syringes made by other manufacturers that were not cleared for the purpose of closed-container storage usage. FDA has received several reports of compounded and repackaged drugs, such as fentanyl, morphine, methadone and atropine, losing potency when stored in BD 3ml and 5ml general purpose syringes. It is possible that this chemical reaction may affect other compounded and repackaged drugs stored in syringes not FDA cleared for closed-container storage.

**RECOMMENDATION:** Hospital and pharmacy staff should check supply stocks and remove drug products that were filled by pharmacies or outsourcing facilities and stored in general purpose BD 3ml and 5ml syringes. These syringes are marked with the BD logo at the base of the syringe. At this time, FDA does not have information on how long drugs can be stored in these syringes before degrading. There is no information to suggest that there is a problem with potency or drug degradation when medication is administered promptly after the syringes are filled.

This warning does not extend to products approved by FDA for marketing as pre-filled syringes, because as part of the approval process, FDA has determined that these products have been shown to maintain stability in the syringe container through the expiration date on the product.

The FDA is continuing to investigate this issue and will provide more information when it is available.

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](http://www.fda.gov/MedWatch/report)
- [Download form](#) 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

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