



State of Wisconsin
Department of Health Services

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Check Your Insulin Syringe

FDA Recalls ReliOn Needles Due to Possible Mislabeling

State health officials are urging people with diabetes and health care professionals to carefully check their insulin syringes. The U.S. Food and Drug Administration (FDA) has recalled one lot of ReliOn sterile, single-use, disposable, hypodermic syringes with permanently affixed hypodermic needles due to possible mislabeling. The use of these syringes may lead to patients receiving an overdose of as much as 2.5 times the intended dose, which may lead to hypoglycemia, serious health consequences, and even death.

ReliOn Insulin Syringes consist of a syringe barrel, a plunger rod, and a hypodermic needle attached to the tip of the syringe. The recall applies to the following lot number and product information:

- Lot Number 813900
- ReliOn 1cc, 31-gauge, 100 units for use with U-100 insulin
- Only ReliOn syringes from this lot number and labeled as 100 units for use with U-100 insulin are the subject of the recall

The manufacturer distributed 4,710 boxes in the recalled lot, which equals 471,000 individual syringes. Wal-Mart sold the syringes at Wal-Mart stores and Sam's Clubs from August 1, 2008, until October 8, 2008.

Wal-Mart requests that all users of the recall lot return the syringes to their local Wal-Mart store or Sam's Club pharmacy. Customers will be provided with replacement product. Consumers and health care professionals who suspect they have the recalled product may also contact Covidien at 866-780-5436 or www.relion.com/recall for more information.

During the packaging process for lot 813900, some syringes labeled for use with U-40 insulin were mixed with syringes labeled for use with U-100 insulin, which were then packaged individually and in boxes as 100 units for use with U-100 insulin. The manufacturer, Tyco Healthcare Group LP (Covidien) voluntarily recalled this lot of syringes on October 9, 2008, asking that any units of the affected product be removed from inventory and placed in quarantine.

To see the FDA's press release, go to <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01911.html>

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