



Accusure Insulin Syringes [31G, 1/2 cc and 1 cc]

08/24/2009

Audience: Patients with diabetes mellitus, pharmacists and diabetes healthcare professionals

Qualitest Pharmaceuticals, Inc.

Issues a Voluntary Nationwide Recall of

Accusure® Insulin Syringes (1/2 Cc – 31 G – Short Needle) Lot #6jcb1

and Accusure® Insulin Syringes (1 Cc – 31 G – Short Needle) Lot #7cpt1

Contact:

Qualitest Pharmaceuticals

Larry Kass

1 (800) 444-4011

FOR IMMEDIATE RELEASE -- August 21, 2009 -- Huntsville, AL - Qualitest Pharmaceuticals, Inc., today has issued a voluntary nationwide recall of Accusure® Insulin Syringes (1/2 cc – 31 G – Short Needle) with lot number 6JCB1 (Expiration 10/2011) – NDC 0603-7001-21. This lot was distributed between January 2007 and June 2007 to wholesalers and retail pharmacies nationwide (including Puerto Rico). Also today, Qualitest has issued a voluntary nationwide recall of Accusure® Insulin Syringes (1 cc – 31 G – Short Needle) with lot number 7CPT1 (Expiration 03/2012) – NDC 0603-7002-21. This lot was distributed between May 2007 and June 2008 to wholesalers and retail pharmacies nationwide (including Puerto Rico). The syringes in these lots have been found to have needles which can detach from the syringe.

When the needle becomes detached from the syringe during use, it can become stuck in the insulin vial, push back into the syringe, or remain in the skin after an injection.

Consumers who have any Accusure® Insulin Syringes (1/2 cc – 31 G – Short Needle) with lot number 6JCB1 or Accusure® Insulin Syringes (1 cc – 31 G – Short Needle) with lot number 7CPT1 should stop using them and contact Qualitest at 1-800-444-4011 for product replacement instructions. You can find the lot number on the white paper backing of each individual syringe.

Qualitest is notifying all customers who received the product and arranging for return of any affected product. This recall is being made with the knowledge of the Food and Drug Administration.

Consumers with questions may contact Qualitest at 1-800-444-4011 for more information.

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

- **Online:** <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>
- **Regular Mail:** use postage-paid FDA form 3500 available at: www.fed.gov/MedWatch/getforms.htm
Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- **Fax:** 1-800-FDA-0178

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