Roche ACCU-CHEK FlexLink Plus Infusion Set: Class I Recall - Potential for Under-Delivery of Insulin

U.S. Food & Drug Administration

AUDIENCE: Endocrinology, Patients

ISSUE: There is a potential for under-delivery of insulin due to a tube (cannula) which may become kinked or bent when inserting the ACCU-CHEK FlexLink Plus infusion set. If this remains unnoticed, this can result in under-delivery or no delivery of insulin. This can lead to elevated blood glucose levels (hyperglycemia). Hyperglycemia can lead to many serious health complications including death.

BACKGROUND: This recall only applies to the ACCU-CHEK FlexLink Plus infusion sets that were launched in November 2010. ACCU-CHEK Ultraflex, other Accu-Chek infusion sets or insulin pumps are not affected by this recall and can be continued as directed by a physician or other qualified health care provider.

RECOMMENDATION: The company requested its customers to stop using the ACCU-CHEK FlexLink Plus infusion sets and return the unused products. Patients are to contact their health care providers or caregivers to determine if changes to their therapy are needed and how to temporarily continue insulin pump therapy without the ACCU-CHEK FlexLink Plus infusion set.

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

[03/29/2011 - Recall Notice [3] - FDA]
[02/21/2011 - Press Release [4] - Roche Insulin Delivery Systems, Inc.]

SOURCE [5]

Source URL (retrieved on *09/18/2014 - 6:44pm*):
http://www.mdtmag.com/news/2011/03/roche-accu-chek-flexlink-plus-infusion-set-class-i-recall-potential-under-delivery-insulin

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/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm248772.htm
[4] http://www.fda.gov/Safety/Recalls/ucm244487.htm
[5] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm248784.htm