

December 22, 2010

FDA Safety Announcement: Abbott Glucose Test Strips: Recall - False Low Blood Glucose Results

including Precision Xceed Pro, Precision Xtra, Medisense Optium, Optium, OptiumEZ, ReliOn Ultima

AUDIENCE: Endocrine, Patients, Pharmacy

ISSUE: The FDA and Abbott Diabetes Care are working to notify healthcare professionals and patients regarding the recall of 359 different lots of glucose test strips marketed under the following brand names: Precision Xceed Pro, Precision Xtra, Medisense Optium, Optium, OptiumEZ and ReliOn Ultima. The issue relates to the insufficient absorption of blood into the test strip. Strips that have either been exposed to warm weather or prolonged storage may have a higher likelihood of providing a false result. Test strips included in the recall may give falsely low blood glucose results, which can lead patients to try to raise their blood glucose when it is unnecessary, or to fail to treat elevated blood glucose due to a falsely low reading. Both scenarios pose risks to health.

BACKGROUND: The recalled test strips are used with Abbott's Precision Xtra, Precision Xceed Pro, MediSense Optium, Optium, Optium EZ and ReliOn Ultima blood glucose monitoring systems. As many as 359 million strips may be affected by the recall. The test strips, which were manufactured between January and May 2010, are sold both in retail and online settings directly to consumers, but are also used in health care facilities.

RECOMMENDATION: The FDA is releasing recommendations for consumers and healthcare professionals. These recommendations explain how to determine whether a particular lot is affected, how to order a free replacement set of strips, and what steps to take in the meantime.

Patients with diabetes should be aware of this problem and take steps to prevent it from affecting their health. Customers can check if they have tests trips from the recalled lots by visiting Abbott's website to look up their product lot number: <http://www.precisionoptiuminfo.com>

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
- [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

Read the MedWatch safety alert, including links to the News Release and FDA Questions and Answers, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm237910.htm>

www.kcercoalition.com/alerts.htm

