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Counterfeit Blood Glucose Test Strips by Sangeeta Naidu

On October 13, 2006, the Food and Drug Administration (FDA) issued a public warning regarding counterfeit One Touch brand blood glucose test strips being sold in the United States. LifeScan, the manufacturer of One Touch, notified the FDA of the counterfeit strips. The affected test strips include OneTouch Ultra and OneTouch (Basic/Profile). The OneTouch FastTake and the OneTouch SureStep test strips are not involved.^{1, 2}

Champion Sales in New York and Quebec-based Medical Plastic Devices distributed the counterfeit strips to pharmacies in the United States. These strips were distributed mainly in Maryland, Missouri, Ohio, Florida, and New York. The counterfeit strips have not been distributed in Canada. The FDA is not aware of the number of counterfeit strips that have been sold.^{3, 4}

Testing of the counterfeit strips by

LifeScan showed unpredictable blood glucose values that did not meet manufacturer specifications. These counterfeit strips could possibly give incorrect blood glucose readings, resulting in inappropriate insulin dosing that may result in injury or death. Patients are advised to stop using any counterfeit strips and replace them at once. Patients are also advised to let their physician know of any possible complications that may have resulted from using the counterfeit strips. LifeScan will not reimburse pharmacies and retailers for these counterfeit strips. Pharmacies and retailers need to contact their original supplier to receive compensation.^{1, 2}

The counterfeit strip lot numbers involved are OneTouch Ultra lot numbers 2691191, 2691261; and OneTouch (Basic/Profile) lot numbers 2606340, 2619932, 272894A, and 2615211. Table 1 details how to determine if strips may be counterfeit.²

Adverse reactions or quality problems from these counterfeit strips should be reported to the FDA's MedWatch program. LifeScan and the FDA are working vigorously to determine the source and to put an end to these counterfeit strips. In the meantime, consumers and health-care professionals need to be on the alert for these counterfeit strips.¹

References:

1. FDA Updates its Nationwide Alert on Counterfeit Blood Glucose Test Strips. Retrieved Oct. 28, 2006, from <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01497.html>.
2. Counterfeit Product Alert. Retrieved Oct. 28, 2006, from <http://www.LifeScan.com/company/about/press/counterfeit>.
3. Counterfeit blood glucose test strips found on U.S. market. Retrieved Oct. 28, 2006, from http://www.cbc.ca/consumer/recalls/2006/10/counterfeit_blood_glucose_test.html.
4. FDA Issues Nationwide Alert on Counterfeit One Touch Basic/Profile and One Touch Ultra Blood Glucose Test Strips. Retrieved Oct. 28, 2006, from <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01490.html>.

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Table 1: Identifying Counterfeit Strips²

Test strip	Lot Number	What to Look For
OneTouch Ultra	2691191	English, French text Lot# on vial label, carton 50 count strip package No NDC number
OneTouch Ultra	2691261	Same as lot#2691191
OneTouch (Basic/Profile)	2606340	English, Greek, Portuguese text Lot# on vial label, carton 50 count strip package No NDC number
OneTouch (Basic/Profile)	2619932	Same as lot#2606340
OneTouch (Basic/Profile)	272894A	Same as lot#2606340
OneTouch (Basic/Profile)	2615211	English text 50 count strip package No NDC number Picture of a finger on carton

Januvia™ - A New Choice in Treating Diabetes by Michael Dvorak

In October 2006, the FDA approved a new medication indicated for treatment of type 2 diabetes. Sitagliptan (Januvia™-Merck) is a member of a new drug class called the dipeptidyl peptidase IV (DPP-IV) inhibitors.¹ The DPP-IV inhibitors have a unique mechanism that acts on the incretin system in the body. When the body takes in a large amount of glucose, as with a meal, it releases glucagon-like peptide 1 (GLP-1). GLP-1 stimulates insulin secretion, leading to the lowering of glucose levels. Sitagliptan inhibits DPP-IV, increasing the half-life of GLP-1 and allowing for more insulin secretion and better overall glucose control.²

Sitagliptan's indication includes the use of diet and exercise in addition to drug therapy for glucose control in type 2 diabetes. It can be used as monotherapy or also in combination with other oral diabetic therapies like metformin and thiazolidinediones.

Sitagliptan is available as a tablet in three strengths: 25 mg, 50 mg, and 100 mg. The approved dose of sitagliptan is 100 mg once daily.

Food has not been shown to affect absorption of the drug. Sitagliptan is approximately 80% excreted unchanged in the urine, and must be adjusted in patients with renal impairment. Patients with a CrCl of between 30-50ml/min should receive 50 mg once daily and patients with CrCl below 30 ml/min should be dosed at 25 mg once daily. Sitagliptan was well tolerated in clinical trials, with the most common adverse effects being nasopharyngitis, upper respiratory infection, and headache. Hypoglycemia with sitagliptan was not significantly different from placebo in clinical trials. Digoxin is the only drug that has been shown to interact with sitagliptan, leading to increased digoxin levels. No dosage adjustments for this interaction have been recommended. Sitagliptan is a pregnancy category B.²

Sitagliptan does not require any special monitoring.⁴

Cost may be of concern with sitagliptan therapy. It is estimated to cost approximately \$145 for a 30 day supply.² Sitagliptan is another step forward in the fight to control type 2 diabetes. It has a different mechanism of action compared to other medications currently on the market and is considered well tolerated.

References:

1. FDA approves new treatment for diabetes. Available from: <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01492.html>.
2. Herman GA, Stevens C, Van Dyck K, et. al. Pharmacokinetics and pharmacodynamics of sitagliptan, an inhibitor of dipeptidyl peptidase IV, in healthy subjects: Results from two randomized, double-blind, placebo controlled studies with single oral doses. *Clin Pharmacol Ther* 2005;78 (6):675-88.
3. New Drug: Sitagliptan (Januvia). *Pharmacist's Letter* 2006; vol. 22 no. 221102.
4. Januvia (sitagliptin phosphate) tablets [product information]. Whitehouse Station (NJ): Merck & Co., Inc, 2006. Available from: http://www.januvia.com/sitagliptin_phosphate/januvia/hcp/pi/index.jsp.

FDA Warns Against Ibuprofen and Aspirin Combination by Diana Cadaoas

In September 2006, the FDA issued a warning regarding an interaction associated with the concomitant use of ibuprofen and low-dose aspirin.

Studies have demonstrated a pharmacodynamic interaction between ibuprofen 400mg and low dose (81mg) aspirin exists, which may interfere with the antiplatelet activity of aspirin as measured by thromboxane B2 levels and platelet activation.

In single dose ibuprofen studies, ibuprofen interfered with the antiplatelet activity of low dose immediate release aspirin when taken together. The mechanism of this drug interaction is due to ibuprofen interfering with aspirin binding, as both bind to nearby sites on the COX enzyme. Data from unpub-

lished single dose trials evaluating aspirin's antiplatelet activity suggest that single doses of ibuprofen should be given at least 8 hours before or at least 30 minutes after immediate release low dose aspirin.

The FDA has published information for healthcare professionals regarding the appropriate use of ibuprofen and aspirin concurrently. The following should be considered:

- There is likely to be minimal risk of attenuation of anti-platelet effects of low dose aspirin with occasional use of ibuprofen
- Patients using immediate-release (non-enteric coated) aspirin and taking a single dose of ibuprofen 400mg should dose the ibuprofen at least 30 minutes or longer after aspirin ingestion, or more than 8 hours before aspirin ingestion

- Other non-selective OTC NSAIDs should be viewed as having similar interaction potential with low-dose aspirin unless proven otherwise
- Prescribing analgesics that do not interfere with aspirin's antiplatelet effect may be appropriate for high risk populations
- Recommendations regarding the use of ibuprofen and enteric-coated low dose aspirin cannot be made based upon available data

Although the clinical implication of this interaction is unclear, the possibility that the cardioprotective secondary prevention of myocardial infarction may be impacted is concerning.

Reference:

FDA. Concomitant Use of Ibuprofen and Aspirin: Potential for Attenuation of the Anti-Platelet Effect of Aspirin. Food and Drug Administration Science Paper. [created 2006 Sep 9; accessed 2006 Oct 30]. Available from <http://www.fda.gov/cder/drug/infopage/ibuprofen/science_paper.htm>

AHRQ Analysis of Arthritis Medications by Kevin Fuji

As part of the Agency for Healthcare Research and Quality's (AHRQ) Effective Health Care Program, an analysis of 360 studies on 26 agents for the treatment of osteoarthritis was performed, and their benefits and harms compared. The AHRQ seeks to provide valid evidence of different medical interventions through comparative analysis. Its objective is to help health-care providers, consumers, and others in making informed choices among alternative treatments.

Oral medications included in this analysis were NSAIDs, acetaminophen, COX-2 inhibitors, aspirin and glucosamine-chondroitin supplements. Results indicated that no currently available analgesic offers a clear overall advantage compared with the others. The one exception to this is naproxen, which appears to have a lower risk of heart attack than the other agents.¹

The two main types of osteoarthritis agents, COX-2 inhibitors and NSAIDs, were found to be equally effective for pain relief and have comparable side effect profiles. Both groups can cause or worsen high blood pressure, congestive heart failure, swelling, or poor kidney function. There is also evidence of increased cardiovascular and GI side effects in older patients, as well as in

patients with pre-existing heart and kidney problems. However, in specific patient populations, COX-2 inhibitors do appear to have less of an effect on GI bleeding than NSAIDs.¹

Topical NSAIDs were similar to oral NSAIDs for pain relief, but had a greater number of local adverse effects. Topical diclofenac DMSO (dimethyl sulphoxide) was the most well studied topical NSAID, but is not approved for use in the US.¹



In regard to glucosamine-chondroitin supplements, there is evidence that they may reduce pain without the risks associated with NSAID and COX-2 inhibitor use. However, many of the formulations studied were of pharmaceutical-

grade glucosamine that is currently only available in Europe.¹

The researchers concluded that additional long-term trials will need to be performed in order to better assess the current treatments available. Because the amount and quality of evidence varies from one agent to another, different factors must be taken into account when weighing the benefits of a particular analgesic. For instance, in a particular patient, increased cardiovascular risk may be an acceptable trade-off for increased adequate pain relief, whereas in another patient, any amount of increased cardiovascular risk is unacceptable. Age, comorbid conditions, and concomitant medication use are other factors that should be considered when selecting an analgesic for a patient. Until more evidence emerges with these agents, tailoring therapy in a patient-specific manner appears to be the best option.¹

Reference:

1. Chou R, Helfand M, Peterson K, Dana T, Roberts C. Comparative Effectiveness and Safety of Analgesics for Osteoarthritis. Comparative Effectiveness Review No. 4. Rockville, MD: Agency for Healthcare Research and Quality. September 2006.

Help for Nebraska Seniors—The SHIP Program

Medicare concerns and other insurance questions can become a great difficulty for seniors, their family and caregivers, and health care providers. The Nebraska Senior Health Insurance Program (SHIP) is available to assist on topics related to Medicare and other senior health insurance issues.

The mission of the SHIP program is to inform, educate and assist consumers in these areas. Regional staff members, as well as more than 300 trained volunteers, are available to help seniors throughout the state.

General consumer education, as well as one-on-one counseling, is available.

The SHIP program provides general information through presentations, health fairs, senior centers, printed materials and radio and television advertisements. However, persons needing individualized assistance may also receive personalized counseling in the following areas:

- Answering questions
- Solving problems
- Receiving support
- Obtaining referrals
- Policy analysis
- Claims problems

The SHIP program is housed within the Nebraska Department of Insurance, and is provided in part by the Centers for Medicare and Medicaid Services (CMS). In the Omaha area, the SHIP program can provide one-on-one counseling and assistance to Medicare beneficiaries, their caregivers and families, as well as professionals.

For more information, the SHIP program can be reached statewide through a toll free hotline at 1-800-234-7119.

ER Visits Secondary to Medications by Kevin Ronnenkamp

Results from the National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance (NEISS-CADES) project were published in the Journal of the American Medical Association last month, reporting that more than 700,000 people are estimated to have visited the emergency room secondary to adverse drug events in 2004 and 2005.¹ The NEISS-CADES is a joint effort of the Centers for Disease Control and Prevention (CDC), US Consumer Product Safety Commission (CPSC) and the U.S. Food and Drug Administration (FDA).

Based on the surveillance project, it is estimated



that 2.4 individuals per 1000 population were treated in emergency rooms for adverse drug events. Data suggest that adverse drug events account for approximately 2.5% of total emergency room visits for unintentional injuries and 6.7% of emergency room visits resulting in hospitalization. Individuals over the age of 65 were more likely than younger patients to both visit an emergency room and be hospitalized secondary to adverse drug events.

The drug classes most commonly implicated in adverse drug events were insulins, opioid-containing analgesics, anti-coagulants, amoxicillin-containing agents and antihistamines/cold remedies. These five categories of drugs accounted for more than 27% of estimated adverse drug events. The most common conditions caused were dermatologic, gastrointestinal or neurologic in nature.

This surveillance study documents the importance of adverse drug events as a cause of morbidity in the United States, particularly among the older population. Surveillance programs such as this may

help to identify prevention strategies.

Reference:

Budnitz DS, Pollock DA, Weidenbach KN, et al. National surveillance of emergency department visits for outpatient adverse drug events. *JAMA* 2006;296(15):1858-66.



Best wishes for a joyous holiday season from the Creighton Drug Information Center!



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