



## MEMORANDUM

To: Facility Manager

From: Lana Kacherova, QI Director  
Lisle Mukai, QI Coordinator

Subject: **FDA Recalls & Alerts**

Date: September 8, 2009

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The Network is required to distribute information regarding recalls and alerts that potentially affect ESRD facilities and/or patients.

Please review the attached documents:

- Myfrotic (mycophenolica acid) [1 page] – **SAFETY ALERT**
- Accusure Insulin Syringes (31G, ½cc, and 1cc) [1 page] – **RECALL**
- Serious Errors with Certain Blood Glucose Monitoring Test Strips – For Diabetic Patients and/or Their Caregivers [3 pages] – **SAFETY ALERT**
- FDA Public Health Notification: Potentially Fata Errors with GHD-PQQ Glucose Monitoring Technology [3 pages] – **SAFETY ALERT**

Please share this information as applicable within your organizations/practices.

Thank you for your time and attention to this important patient safety issue.

Cc: Steven Preston, Project Officer, CMS RO X

### Mission Statement

*To provide leadership and assistance to renal dialysis and transplant facilities in a manner that supports continuous improvement in patient care, outcomes, safety and satisfaction.*



## Myfortic (mycophenolic acid)

**Audience:** Renal, cardiac, and hepatic transplantation healthcare professionals

[Posted 09/03/2009] Novartis and FDA notified healthcare professionals that cases of Pure Red Cell Aplasia (PRCA) have been reported in patients treated with Myfortic. The WARNINGS and ADVERSE REACTIONS sections of the Myfortic Prescribing Information have been revised to reflect this new safety information.

PRCA is a type of anemia in which there is a selective reduction of red blood cell precursors on bone marrow examination. Patients with PRCA may present with fatigue, lethargy, and/or abnormal paleness of the skin (pallor). In some cases, PRCA was found to be reversible with dose reduction or cessation of Myfortic therapy. In transplant patients, however, reduced immunosuppression may place the graft at risk.

Novartis Pharmaceuticals Corporation would like to inform you that new postmarketing safety information has been added to the **WARNINGS** and **ADVERSE REACTIONS** sections of the *myfortic* Prescribing Information. Cases of pure red cell aplasia (PRCA) have been reported in patients treated with mycophenolate mofetil (MMF) in combination with other immunosuppressive agents. MMF is converted to mycophenolic acid (MPA), the active ingredient in *myfortic*, following oral or IV administration.

The new important safety information in the *myfortic* Prescribing Information includes: **“WARNINGS (SEE BOXED WARNING) Pure Red Cell Aplasia.** Cases of pure red cell aplasia (PRCA) have been reported in patients treated with mycophenolate mofetil (MMF) in combination with other immunosuppressive agents. MMF is metabolized to mycophenolic acid (MPA), the active ingredient in Myfortic and the active form of the drug. The mechanism for MMF induced PRCA is unknown; the relative contribution of other immunosuppressants and their combinations in an immunosuppressive regimen are also unknown. In some cases PRCA was found to be reversible with dose reduction or cessation of MMF therapy.

In transplant patients, however, reduced immunosuppression may place the graft at risk. Changes to Myfortic therapy should only be undertaken under appropriate supervision in transplant recipients in order to minimize the risk of graft rejection (see ADVERSE REACTIONS, Postmarketing Experience).

The complete revised Prescribing Information and Medication Guide can be found on the Internet at <http://www.myfortic.com>. Contact Novartis if you have any questions about this information or the safe and effective use of *myfortic*.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of *myfortic* to Novartis Pharmaceuticals Corporation, One Health Plaza, East Hanover, NJ 07936 or by phone at 1-888-NOW-NOVA (1-888-669-6682), Monday through Friday from 8:30 AM - 5:00 PM EST

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## 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](http://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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## Serious Errors with Certain Blood Glucose Monitoring Test Strips – For Diabetic patients and/or their caregivers

August 13, 2009

### Advice

**NEVER use GDH-PQQ\* glucose meters or test strips if you are using drug products or therapies that contain certain sugars other than glucose.**

*\*GDH-PQQ stands for glucose dehydrogenase pyrroloquinoline quinine*

### Issue

Diabetic patients who receive drug products or therapies containing certain sugars other than glucose could experience serious, although rare, injuries if they use blood glucose meters with a particular type of test-strip technology. Strips that use this technology, known as GDH-PQQ, will react with certain non-glucose sugars, including maltose, galactose and xylose, and produce a falsely high (elevated) result. If a diabetic patient then takes too much insulin because of this falsely high result, it could lead to abnormally low blood sugar (hypoglycemia), coma, or even death.

Certain patients may be more likely to be using drug products or therapies that contain other sugars, including those who:

- are on peritoneal dialysis
- have recently had surgery

*Glucose test strips other than the GDH-PQQ type are not affected by this problem, and can be used by patients taking drug products or therapies that contain non-glucose sugars.*

### Drug products or therapies with non-glucose sugars

- Extraneal (icodextrin) peritoneal dialysis solution
- Some immunoglobulins: Octagam 5%, Gamimune N 5% \*\*, WinRho SDF Liquid, Vaccinia Immune Globulin Intravenous (Human) and HepaGamB
- Orencia (abatacept)
- Adept adhesion reduction solution (4% icodextrin)
- BEXXAR radioimmunotherapy agent
- Any product that contains, or the body breaks down into, the sugars maltose, galactose or xylose

*\*\* Within the U.S., Gamimune N 5% has not been manufactured since December 2005, and no lots are in distribution in the U.S.*

### Patient concerns

If you are taking drug products or therapies that contain certain non-glucose sugars, such as maltose, galactose and xylose, these sugars will produce a falsely elevated glucose result if you are measuring your blood glucose using a GDH-PQQ test strip. If you then use this falsely elevated result to determine your dose of insulin, you could give yourself too much insulin, which could result in dangerously low blood glucose. In addition, if your blood glucose is actually low, it could go unrecognized and untreated because the test result could read higher



than it actually is and appear to be within the normal range. In this case, you may not know your blood glucose is low unless you have certain symptoms, including confusion, hunger, nervousness, dizziness, irritability, sweating, heart pounding (palpitations), shaking, unusual fatigue or weakness, or tunnel or darkened vision. Low blood glucose must be recognized and treated promptly to avoid serious complications, such as coma and death.

### **Recommendations for diabetic patients using interfering drug products or therapies**

If you are a diabetic patient who uses any of the drug products or therapies that contain certain non-glucose sugars (or care for someone who does), you should:

- **NEVER** use GDH-PQQ glucose meters or test strips.
- Instead, use another type of glucose monitoring technology and continue to monitor your blood glucose as instructed by your healthcare provider.
- Contact your healthcare provider if your results do not reflect the way you feel.

You may be able to determine the type of glucose monitoring technology you are using by looking at the instructions that accompanied your meter or test strips, or at your meter's box. If you can't tell what kind of technology your meter and test strips use, ask your healthcare provider or pharmacist to help you find out, and/or contact the manufacturer of your meter and test strips.

### **General recommendations for all diabetic patients**

- Continue testing your blood glucose as directed by your healthcare provider.
- Use only test strips specified for your glucose meter.
- Know the type of glucose monitoring technology you are using.
- Know that GDH-PQQ meters and strips should NOT be used if you are using an interfering drug product or therapy.
- Know that GDH-PQQ meters and strips are okay to use if you are not using an interfering drug product or therapy.
- Know the medications you are taking and keep a current list of your medications. If you do not have a current list of medications, ask your healthcare provider to provide you with a list.

### **Questions to ask your healthcare provider**

- How do I determine which glucose meter and strips I have?
- Which drugs am I currently taking? Am I taking or receiving an interfering drug product or therapy?
- Should I continue testing my blood glucose with my current meter and strips or should I get a new meter and strips? If so, how do I do this?



## List of GDH-PQQ Glucose Test Strips

The following test strips (with associated meters) use GDH-PQQ methodology as of August 2009:

### **Roche Diagnostics:**

1. ACCU-CHEK Comfort Curve test strips, for use with:
  - ACCU-CHEK Inform meters [model 2001201]
  - ACCU-CHEK Complete meters [models 200 and 250]
  - ACCU-CHEK Advantage meters [models 888, 831, 850, and 768]
  - ACCU-CHEK Voicemate meters [model 0009221]
2. ACCU-CHEK Aviva test strips, for use with:
  - ACCU-CHEK Aviva meters [models 525, 535, and 555]
3. ACCU-CHEK Compact test strips, for use with:
  - ACCU-CHEK Compact meters [model GF]
  - ACCU-CHEK Compact Plus meters [models GP and GT]
4. ACCU-CHEK Go test strips
  - ACCU-CHEK Go meters [model GJ]
5. ACCU-CHEK Active test strips
  - ACCU-CHEK Active meters [models GG and GN]

### **Abbott Diabetes Care:**

1. Freestyle test strips, for use with:
  - FreeStyle meters
  - FreeStyle Flash meters
  - FreeStyle Freedom meters
2. Freestyle Lite test strips, for use with:
  - FreeStyle Lite meters
  - FreeStyle Freedom Lite meters

### **Home Diagnostics:**

1. TRUEtest test strips
  - TRUEresult meters
  - TRUE2go meters

### **Smiths Medical:**

1. Abbott Diabetes Care Freestyle test strips, for use with:
  - CoZmonitor blood glucose module (for use with the Deltec Cozmo Insulin Pump)

### **Insulet:**

1. Abbott Diabetes Care Freestyle test strips, for use with:
  - OmniPod Insulin Management System

*Note: Test strips currently on the market may be distributed under multiple trade names. In addition, manufacturers of GDH-PQQ test strips currently on the market may subsequently change to non-GDH-PQQ methodology. Therefore, healthcare providers (and patients) should refer to device labeling or consult with test strip manufacturers to confirm the type of methodology used.*

###

# FDA Public Health Notification: Potentially Fatal Errors with GDH-PQQ\* Glucose Monitoring Technology

\* *glucose dehydrogenase pyrroloquinoline quinone*

**Date: August 13, 2009**

Dear Healthcare Practitioner:

This is to alert you to the possibility of falsely elevated blood glucose results when using GDH-PQQ glucose test strips on patients who are receiving therapeutic products containing certain non-glucose sugars. These sugars can falsely elevate glucose results, which may mask significant hypoglycemia or prompt excessive insulin administration, leading to serious injury or death. The following provides background information on this problem, a summary of fatality reports FDA has received, and recommendations to reduce the risk. This problem can occur wherever these products are used including in-patient and out-patient healthcare facilities, and at home.

## **Nature of the problem**

GDH-PQQ glucose monitoring measures a patient's blood glucose value using methodology that cannot distinguish between glucose and other sugars. Certain non-glucose sugars, including maltose, xylose, and galactose, are found in certain drug and biologic formulations, or can result from the metabolism of a drug or therapeutic product.

When these non-glucose sugars are present in the patient's blood, using a GDH-PQQ glucose test strip will produce an elevated glucose result which may suggest the need for clinical action. This can lead to inappropriate dosing and administration of insulin, potentially resulting in hypoglycemia, coma, or death.

In addition, cases of actual hypoglycemia may go unrecognized if the patient and healthcare practitioner rely solely on the test result obtained with the GDH-PQQ glucose test strips.

**Other glucose test strip methodologies are not affected by the presence of non-glucose sugars**. The unaffected methods are glucose oxidase, glucose dehydrogenase nicotinic adenine dinucleotide (GDH-NAD), or glucose dehydrogenase flavin adenine dinucleotide (GDH-FAD).

Laboratory-based blood glucose assays do not use GDH-PQQ methodology and are not subject to falsely elevated results from non-glucose sugars.

## **Recommendations**

- Avoid using GDH-PQQ glucose test strips in healthcare facilities.  
[List of GDH-PQQ Glucose Test Strips](#)
- If your facility currently uses GDH-PQQ glucose test strips, NEVER use them on patients:
  - who are receiving interfering products\*\*, or
  - from whom or about whom you cannot obtain information regarding concomitant medication use, e.g., patients who are unresponsive or cannot adequately communicate.

\*\*Interfering products containing non-glucose sugars include:

- Extraneal (icodextrin) peritoneal dialysis solution
- Some Immunoglobulins: Octagam 5%, Gamimune N 5%\*\*\*, WinRho SDF Liquid, Vaccinia Immune Globulin Intravenous(Human), and HepaGamB
- Orenzia (abatacept)
- Adept adhesion reduction solution (4% icodextrin)
- BEXXAR radioimmunotherapy agent
- Any product containing, or metabolized into maltose, galactose or xylose.

Use ONLY laboratory-based glucose assays on these patients.

- Determine whether patients are receiving interfering products on admission and periodically during their stay at your facility.
- Educate staff and patients about the potential for falsely elevated glucose results in the presence of certain non-glucose sugars when using GDH-PQQ glucose test strips.
- Consider using drug interaction alerts in computer order entry systems, patient profiles and charts to alert staff to the potential for falsely elevated glucose results.
- Periodically verify glucose meter results with laboratory-based glucose assays if you are using GDH-PQQ test strips in patients who are not receiving interfering products.

\*\*\* *Within the U.S., Gamimune N 5% has not been manufactured since December 2005, and no lots are in distribution in the U.S.*

In addition, an [Advice for Patients](#)<sup>1</sup> can be found on the FDA Consumer website.

## Reports received by FDA

From 1997-2009, FDA received 13 reports of death associated with GDH-PQQ glucose test strips in which there was documented interference from maltose or other non-glucose sugars. Six of the 13 deaths have occurred since 2008 despite FDA's efforts to communicate the risk. The deaths occurred in healthcare facilities. Ten of the 13 patients were receiving Extraneal (icodextrin) peritoneal dialysis solution for renal failure. Three of the 13 patients were receiving maltose-containing substances; one was receiving Potacor R, one was receiving Octagam (IVIG), and another was receiving an infusion that contained maltose. Patients were treated with insulin doses or insulin drips that were guided by falsely elevated results.

Eight reports specified that test result values generated on GDH-PQQ test strips were 3 to 15 times higher than corresponding laboratory results. For example, in one patient the GDH-PQQ system generated a result of 200 mg/dL while the laboratory result was 19 mg/dL. In another case, a patient undergoing peritoneal dialysis with Extraneal was tested with a GDH-PQQ test strip which gave a result of 193 mg/dL, while the result obtained using a laboratory instrument was 8 mg/dL.

Some reports indicated that serious patient injury, such as hypoglycemia, confusion, neurologic deterioration, severe hypoxia, brain damage, and coma occurred prior to death.

FDA is working with manufacturers to address patient safety problems with GDH-PQQ glucose test strips and will continue to monitor adverse events associated with these products.

### **Reporting adverse events**

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect a reportable adverse event associated with a glucose meter or glucose test strip, you should follow the reporting procedure established by your facility. Prompt reporting of adverse events can improve FDA's understanding of and ability to communicate the risks associated with devices and assist in the identification of potential future problems associated with medical devices. If you suspect a falsely elevated blood glucose value associated with a non-glucose sugar interference, include information about the associated drug or biologic product in your adverse event report.

We also encourage you to report any medical device adverse events related to glucose meters or glucose test strips that do not meet the requirements for mandatory reporting. You can report these directly to the device manufacturer or to MedWatch, the FDA's voluntary reporting program. This can be done online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm><sup>2</sup>, by phone at 1-800-FDA-1088, by FAX at 1-800-FDA-0178; or by mailing FDA form 3500 (download from <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms><sup>3</sup>) to MedWatch, 5600 Fishers Lane, Rockville, MD 20857-9787.

### **Getting more information**

If you have questions about this Notification, please contact FDA's Office of Surveillance and Biometrics by e-mail at [phann@fda.hhs.gov](mailto:phann@fda.hhs.gov) or by phone at 301-796-6640.

FDA Medical Device Public Health Notifications are available on the Internet at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications><sup>4</sup>. You can also be notified through email each time a new Public Health Notification is added to our web page. To subscribe, visit: [http://service.govdelivery.com/service/subscribe.html?code=USFDA\\_39](http://service.govdelivery.com/service/subscribe.html?code=USFDA_39)<sup>5</sup>.

Sincerely yours,

Daniel G. Schultz, MD  
Director  
Center for Devices and Radiological Health  
Food and Drug Administration

## Related Links

- [FDA Patient Safety News October 2008. Potentially Fatal Glucose Monitoring Errors with Icodextrin](#)<sup>6</sup>
  - [FDA Drug Safety Newsletter Summer 2008. Volume 1, Number 4. Icodextrin \(marketed as EXTRANEAL\) and Point-of-Care Glucose Monitoring.](#)<sup>7</sup>
  - [Institute for Safe Medication Practices \(ISMP\) Medication Safety Alert! June 19, 2008. FDA Advise-ERR: Prevent dangerous drug-device interaction causing falsely elevated glucose levels.](#)<sup>8</sup>
  - [FDA Center for Biologics Evaluation and Research April 17, 2008. Fatal Iatrogenic Hypoglycemia: Falsely Elevated Blood Glucose Readings with a Point-of-Care Meter Due to a Maltose-Containing Intravenous Immune Globulin Product.](#)<sup>9</sup>
  - [FDA Patient Safety News February 2006 and September 2006. Avoiding Glucose Monitoring Errors in Patients Receiving Other Sugars.](#)<sup>10</sup>
  - [FDA MedWatch Safety Alert 2005. Parenteral Maltose/Parenteral Galactose/Oral Xylose-Containing Products.](#)<sup>11</sup>
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