



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.

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