The Florida ESRD Network

FDA Public Health Notification: Potentially Fatal Errors with GDH-PQQ* Glucose Monitoring Technology **glucose dehydrogenase pyrroloquinoline quinine*

August 13, 2009:

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.

- 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 nicotine 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.
- 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
    - Orencia (abatacept) , Adept adhesion reduction solution (4% icodextrin),
    - BEXXAR radioimmunotherapy agent
    - Any product containing, or metabolized into maltose, galactose or xylose.
  - 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.

A **list of GDH-PQQ Glucose Test Strips** and **additional information** can be found at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm177295.htm

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