

IMPORTANT DRUG WARNING

October 19, 2005

Dear Healthcare Professional

This letter is intended to alert physicians, nurses, pharmacists and other healthcare professionals of the potential for falsely elevated glucose readings when using certain blood glucose testing systems that are not glucose-specific (for example, glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase based blood glucose monitoring systems) in patients who have received maltose-containing parenteral products, including Octagam® [Immune Globulin Intravenous (Human) 5% Solvent / Detergent Treated].

Although this drug-device interaction is known and is identified in the Octagam® package insert (1-5), there have been reports of the inappropriate administration of insulin and subsequent life-threatening / fatal hypoglycemia following blood glucose testing using the GDH-PQQ based method.

Some point-of-care glucose test systems, including the GDH-PQQ and glucose-dye-oxidoreductase methods of glucose determination, are non-specific for glucose. In the presence of maltose in sufficient concentrations, these testing systems will report falsely elevated glucose readings, and this has resulted in the inappropriate and life-threatening administration of insulin. Also, cases of true hypoglycemia may go untreated if the hypoglycemic state is masked by the false elevation of blood glucose readings. As hypoglycemia may be life threatening, it is important that clinicians and other health care professionals prescribing and/or administering maltose-containing parenteral products, including Octagam®, be aware of the potential of certain blood glucose testing systems to falsely interpret maltose as glucose. Accordingly, you should ensure the type of blood glucose testing system that is used in patients receiving Octagam®, or other maltose-containing parenteral products, is appropriate for use with such products (for example, glucose oxidase and hexokinase based systems).

In response to the above reports, and in consultation with the FDA, Octapharma will be making the following changes to its package insert for Octagam® [Immune Globulin Intravenous (Human) 5% Solvent / Detergent Treated]:

WARNINGS

Blood Glucose Testing

Some types of blood glucose testing systems (for example, those based on the glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase methods) falsely interpret the maltose contained in Octagam® as glucose. This has resulted in falsely elevated glucose readings and, consequently, in the inappropriate administration of insulin, resulting in life-

threatening hypoglycemia. Also, cases of true hypoglycemia may go untreated if the hypoglycemic state is masked by falsely elevated glucose readings. Accordingly, when administering Octagam® or other parenteral maltose- containing products, the measurement of blood glucose must be done with a glucose-specific method. The product information of the blood glucose testing system, including that of the test strips, should be carefully reviewed to determine if the system is appropriate for use with maltose-containing parenteral products. If any uncertainty exists, contact the manufacturer of the testing system to determine if the system is appropriate for use with maltose- containing parenteral products.

PRECAUTIONS

Drug/Laboratory Test Interactions

Octagam® contains maltose which can be misinterpreted as glucose by certain types of blood glucose testing systems (for example, by systems based on GDH-PQQ or glucose-dye-oxidoreductase methods). Due to the potential for falsely elevated glucose readings, only testing systems that are glucose-specific, should be used to test or monitor blood glucose levels in patients receiving maltose-containing parenteral products, including Octagam®.

The product information of the blood glucose testing system, including that of the test strips, should be carefully reviewed to determine if the system is appropriate for use with maltose-containing parenteral products. If any uncertainty exists, contact the manufacturer of the testing system to determine if the system is appropriate for use with maltose-containing parenteral products (see WARNINGS).

For further information please contact Octapharma Medical Affairs at (866) 766-4860.

Sincerely,



Judi Miller

Medical Affairs Director Octapharma USA Inc. 5885 Trinity Parkway Suite 350 Centreville, VA 20120-1978 Tel: + 1 703 766 4872 Fax: + 1 703 766 4861

REFERENCES

1. Medical Device Alert. Medicines and Healthcare Products Regulatory Agency. April 16, 2003. (<http://www.aodp.org/uploadeddocs/MDA-2003-011.pdf>)
2. Octagam® package insert. (http://217.160.163.235/documents/spc/B.840.002.USA_21.pdf)
3. Accu-Chek test strips package insert (various). Roche Diagnostics. (<http://www.accu chek.com/us/>)
4. Kannan S, Rowland CH, Hockings GI, Tauchmann PM and Blackwell EA. Intragam can interfere with blood glucose monitoring. MJA. 2004;180 (5): 251-252.
5. ISMP Medication Safety Alert! Be aware of false glucose results with point-of-care testing. September 8, 2005 (<http://www.ismp.org/MSAarticles/20050908.htm>)