March 11, 2011

CSL Behring LLC
Medical Affairs
North American Commercial Operations
1020 First Avenue
King of Prussia, PA  19406-0901

Important Drug Warning

SUBJECT:  RISK OF THROMBOTIC EVENTS WITH SUBCUTANEOUS OR INAPPROPRIATE INTRAVENOUS USE OF VIVAGLOBIN®

Dear Healthcare Professional:

CSL Behring in cooperation with the U.S. Food and Drug Administration (FDA) would like to inform you of an important safety update. Post-marketing reports to CSL Behring and FDA indicate that the use of Vivaglobin®, a subcutaneous immune globulin product for treatment of primary humoral immunodeficiency (PI), has been associated with serious thrombotic events. The risk of arterial and venous thrombosis following intravenous Immune Globulin (IGIV) products is well known. We now know that a degree of risk is associated with subcutaneous administration of Vivaglobin®. Intravenous use of Vivaglobin® is not FDA-approved and carries a higher risk. Do not infuse Vivaglobin® intravenously.

The Warnings and Precautions sections of the current prescribing information for Vivaglobin® state that “thrombotic events may occur with use of human immune globulin products.” When reported, risk factors in post-marketing thrombotic event reports for Vivaglobin® have included pre-existing cardiovascular disorders, prior thrombotic event, obesity, oral estrogen use, hyperlipoproteinemia, in-dwelling catheter, and immobility. Hyperviscosity, hypercoagulable disorders, and multiple cardiac risk factors may also confer thrombosis risk in the setting of immune globulin product administration. In all patients receiving Vivaglobin®, physicians and patients should take available precautions to minimize risk, including administration of Vivaglobin® at the minimum rate practicable. Vivaglobin® is for subcutaneous infusion only; follow the instructions for subcutaneous administration in the Full Prescribing Information.
Inform patients of the symptoms of a thrombotic event, including shortness of breath, pain and swelling of a limb, focal neurological deficits, chest pain, and other manifestations of thrombotic and embolic events.

In response to reports that certain IGIV products may have higher levels of procoagulant activity that could predispose patients to thrombosis, CSL Behring developed research assays for product assessment. In-house research testing by CSL Behring laboratories revealed procoagulant activity in Vivaglobin®. The significance of these findings is uncertain.

Please report any adverse event you encounter with a CSL Behring product to CSL Behring U.S. Clinical Safety and Pharmacovigilance: 1-866-915-6958. Please provide the lot number(s) of products associated with reported adverse events whenever possible.

You may also report adverse events to the U.S. Food and Drug Administration at 1-800-FDA-1088, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm, or by mail, using the MedWatch FDA 3500 postage-paid form, to the FDA Safety Information and Adverse Event Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787. Please provide the lot number(s) of products associated with reported adverse events whenever possible.

Click here for Full Prescribing Information for Vivaglobin®: http://www.accessdata.fda.gov/spl/data/be002d84-ee9f-4a1e-a396-3a59a4e5b834/be002d84-ee9f-4a1e-a396-3a59a4e5b834.xml

Sincerely,

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