IMPORTANT SAFETY INFORMATION: Potential Risk of Thrombotic Events with Use of GamaSTAN® S/D (Immune Globulin (Human))

March 23, 2012

Dear Healthcare Professional:

GamaSTAN® S/D, Immune Globulin (Human), is indicated for intramuscular (IM) administration for the treatment of immunoglobulin deficiency, and Hepatitis A, Measles, Varicella and Rubella prophylaxis. The purpose of this letter is to inform you about the potential risk for thrombotic events.

Thrombotic events have been reported in association with immune globulin products. In response to reports that certain intravenous and subcutaneous immunoglobulin products may have elevated levels of procoagulant activity, which can predispose patients to thrombotic events, Grifols conducted in-house research testing that revealed procoagulant activity in GamaSTAN® S/D.

When administering GamaSTAN® S/D please note the labeled instructions and carefully monitor patients for thrombotic events. Off-label administration of GamaStan S/D may increase the risk of thrombotic events. GamaStan S/D should only be administered intramuscularly (IM).

For patients at risk of thrombosis, ensure adequate hydration in patients before administration. Monitor for thrombotic complications and assess baseline blood viscosity in patients at risk for hyperviscosity (including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides) or monoclonal gammopathies. Thrombosis risks include: hypercoagulable conditions, advanced age, prolonged immobilization, history of venous or arterial thrombosis, use of estrogens, in-dwelling vascular catheters, cardiovascular risk factors (including history of atherosclerosis and/or impaired cardiac output,) and hyperviscosity (including cryoglobulins, fasting chylomicronemia/high triglycerols or monoclonal gammopathies).

Important Safety Information

GamaSTAN® S/D, Immune Globulin (Human), is indicated for the treatment of immunoglobulin deficiency, and Hepatitis A, Measles, Varicella and Rubella prophylaxis by intramuscular (IM) injection. GamaSTAN® S/D should not be administered intravenously or subcutaneously because of the potential for serious reactions. Care should be taken to draw back on the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel. Adverse reactions that may occur when GamaSTAN® S/D is used as directed include local pain and tenderness at the injection site, urticaria, and angioedema. Anaphylactic reactions, although rare, have been reported following the injection of human immune globulin preparations. Anaphylaxis is more likely to occur
if GamaSTAN® S/D is given intravenously; therefore, GamaSTAN® S/D must be administered only by intramuscular (IM) injection.

Please report any adverse events you encounter to Grifols Pharmacovigilance: 1-800-520-2807. Please provide the lot number(s) of products associated with adverse events whenever possible.

Please 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 adverse events whenever possible.

Sincerely,

[Signature]

Kenneth Jacobs, M.D.
Senior Medical Director