

July 7, 2017

IMPORTANT CHANGE IN PRESCRIBING INFORMATION IMMUNE GLOBULIN (HUMAN) : GamaSTAN[®] S/D

Revised Dosage Instructions for Hepatitis A Pre and Post exposure Prophylaxis

Dear Healthcare Provider:

Grifols would like to inform you of important changes to the prescribing information for GamaSTAN[®] S/D [Immune Globulin (Human)].

The GamaSTAN[®] S/D prescribing information has been updated with the following changes to the dosing instructions for the hepatitis A pre and post exposure prophylaxis indication:

- GamaSTAN[®] S/D in a dose of **0.05** mL/lb (**0.1** mL/kg) is recommended for household and institutional hepatitis A case contacts.
- The following doses of GamaSTAN[®] S/D are recommended for persons who plan to travel in areas where hepatitis A is common.

Length of Stay	Dose Volume
Up to 1 month	0.1 mL/kg
Up to 2 months	0.2 mL/kg
2 months or longer	Repeat dose of 0.2 mL/kg every two months

For persons traveling for more than 1 month, co-administration with the hepatitis A vaccine may be beneficial. In accordance with "Recommendations of the Advisory Committee on Immunization Practices (ACIP), the hepatitis A vaccine may be administered simultaneously with IG at a separate anatomic injection site.

This dosage change is based on lower concentrations of anti-HAV, due to the decreasing prevalence of previous HAV infection among plasma donors. This change in the dosage recommendations for the Hepatitis A prophylaxis indication will better protect all patients from exposure to the Hepatitis A virus.

This information is also available at

<http://www.hypermunes.com/en/web/hypermunes/hcp/gamastan-hepatitis-a>

Should you have any questions or need additional information, you may contact Grifols by calling Grifols Medical Information toll free at 1-800-520-2807.

Information for Distributors

All distributors of GamaSTAN[®] S/D are required to provide this Change in Prescribing Information to any customers who have received this product.

Sincerely,



Clark Zervos

Vice President, Quality Operations