octapharma
For the safe and optimal use of human proteins

URGENT - Voluntary market withdrawal – September 23, 2010
octagam® [Immune Globulin Intravenous (human)] 5% Liquid Preparation

Dear Healthcare Professional:

On August 20, 2010, in the interest of patient safety, Octapharma USA Inc. initiated a voluntary market withdrawal of selected lots of octagam® [Immune Globulin Intravenous (human)] 5% Liquid Preparation]. This was performed as a result of an increased number of reported thromboembolic events, some of which were serious. A total of 31 lots were voluntarily withdrawn at that time.

Effective immediately, Octapharma USA Inc. is initiating a voluntary market withdrawal of ALL lots of octagam® [Immune Globulin Intravenous (human)] 5% Liquid Preparation] currently in the US market. While Octapharma has not received any reports of thromboembolic events since the August 20, 2010, voluntary market withdrawal was performed, Octapharma has determined, through consultation with the public health authorities at FDA, that until a root cause of the previously reported thromboembolic events can be determined and the problem corrected, the most prudent course of action is to suspend further administration of octagam®.

Thromboembolic events, including stroke, myocardial infarction, pulmonary embolism and deep vein thrombosis have been observed with all intravenous immune globulin products through published literature and post-marketing surveillance. The potential occurrence of these adverse events are listed in all manufacturer package inserts. A copy of the octagam® package insert is enclosed.

Distributors and customers that received octagam® 5% directly from Octapharma are asked to immediately quarantine these lots and contact Octapharma's Customer Service Department for instructions regarding the return of the withdrawn product. If you have further distributed any of these lots of octagam® to other health care providers or facilities, please contact them to quarantine these lots and instruct them to return the affected product to you.

If you are in possession of any product from these lots, whether you are a direct customer of Octapharma or not, please complete the attached Information Form that is included with this letter, and fax a copy of that Information Form to Octapharma's Customer Service Department at 201 604-1141.

We appreciate your immediate attention to this voluntary market withdrawal and sincerely regret any difficulty caused by this action. Most importantly, this voluntary market withdrawal is being performed in the interest of patient safety.

Sincerely,

Tom Schleis, MS, RPh
Director, Medical Affairs
Local Drug Safety Officer
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PLEASE COMPLETE THE FOLLOWING AND FAX TO OCTAPHARMA'S DRUG SAFETY UNIT AND INCLUDE A COPY WITH ALL RETURNS

Fax: 201 604-1141

Voluntary market withdrawal: octagam® [Immune Globulin Intravenous (human)] 5% Liquid Preparation

Name	
Institution	
Address 1	
Address 2	
City	
State and Zip Code	
Telephone Number	
Email	

Lot#	# Vials Purchased	# Vials Used	# Vials Returned

This product has been stored according to conditions listed in the Package Insert for octagam® 5%.

Signed: _____ **Date:** _____

Print Name: _____

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