octapharma®
For the safe and optimal use of human proteins

N O T I C E

URGENT - Voluntary market withdrawal – February 9, 2022
octagam® [Immune Globulin Intravenous (human)] 10% Liquid Preparation]
Lot Numbers K139B8541, K140A8561

Dear Healthcare Professional:

On February 9, 2022 in the interest of patient safety, Octapharma USA, Inc. initiated a voluntary market withdrawal of two lots of octagam® [Immune Globulin Intravenous (Human)] 10% Liquid Preparation]. This was performed as a result of an increased number of reports of hypersensitivity events. All cases resolved without serious injury.

Effective immediately, Octapharma USA Inc. is initiating a voluntary market withdrawal of octagam® 10% [Immune Globulin Intravenous (human)] 10% Liquid Preparation] that is labeled with lot numbers K139B8541 or K140A8561. Octapharma has determined, through consultation with the public health authorities at FDA, the most prudent course of action is to suspend further administration of this Octagam® from these production lots.

Hypersensitivity reactions, including urticaria, wheezing, and anaphylactoid-type responses, have been observed with all intravenous immune globulin products through published literature and post-marketing surveillance. The potential occurrence of these adverse events is listed in all manufacturer package inserts. A copy of the Octagam® package insert is enclosed.

Distributors that received these particular lots of octagam® 10% directly from Octapharma are asked to immediately quarantine this lot and contact Octapharma's Customer Service Department at (866) 766-4860 for instructions regarding the return of the withdrawn product. If you have further distributed this lot of octagam® 10% to health care providers or facilities, please contact them to quarantine these lots and instruct them to return the affected product to you. Please complete the attached Information Form that is included with this letter and email a copy of that Information Form to Octapharma's Customer Service Department at uscustomerservice@octapharma.com.

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.

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octapharma®
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Sincerely,

s/n

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