

**Voluntary Withdrawal of Octagam®  
(immune globulin intravenous [human] 5%)**

**Lot #A732B8431 Exp: 08/09**

**NDC No. 67467 – 843 – 03 / 67467 – 843 - 04**

December 24, 2007

Dear Customer, Doctor, Healthcare Provider:

Octapharma USA Inc. has initiated a voluntary withdrawal of one lot of Octagam® (immune globulin intravenous [human] 5%): Lot # A732B8431

This letter is being written to inform you of this, and to advise you not to administer any product from the lot being withdrawn.

The affected lot comprised 2334 vials and was distributed between 11-27-07 and 12-7-2007.

No other lots of Octagam® are affected by this voluntary withdrawal action.

The company is taking this voluntary action due to the fact that we received several reports about non life-threatening allergic type skin reactions in connection with this lot. In one case the reaction was anaphylactoid in nature and required treatment in the emergency room. In all cases, the patients recovered without sequelae.

No other adverse event reports have been received in connection with this lot.

Cutaneous and immediate anaphylactic, anaphylactoid and hypersensitivity reactions have been observed with Octagam® in clinical studies and during post-marketing surveillance and are listed as adverse reactions on the package insert.

A copy of this can be found at

<http://www.octapharma.com/USA/documents/Octagam%20PI%2030th%20March%202007.pdf>

A detailed internal Quality Assurance and Quality Control review with our manufacturing facility in Vienna, Austria confirms that the product was within all batch release specifications and nothing in the analysis would indicate a higher likelihood of allergic reactions. Nevertheless, as we strive foremost to ensure patient safety, in the light of these isolated cases of allergic reactions, Octapharma has elected to undertake this Voluntary Withdrawal.

Octapharma USA Inc. is working closely with the Food and Drug Administration (FDA) and Center for Biologics Evaluation and Research (CBER) to inform affected customers of this voluntary withdrawal action.

If you have purchased any of the affected lot directly from Octapharma, please return the product to us according to the procedure described below. If you have further distributed this lot of Octagam® to other health care providers or offices, please contact them to ensure that all affected product is returned according to the procedure above.

In order to ensure an effective recall and return process, it is important that you do the following for product purchased directly from Octapharma:

Return all of the unused product, identified above to:

Rx CrossRoads  
Attn: Octapharma Returns  
4500 Progress Boulevard  
Louisville, KY 40245

Please include a packing slip with the returned product indicating the number of vials returned and the institute address and contact details. Credit for all returned product will be issued.

In all cases, i.e. whether you are returning product or not, we would kindly ask you to complete the attached form regarding your utilization of this batch of Octagam®.

In addition, please report any potential Octagam® -related adverse experiences to Octapharma's Drug Safety Unit at 1-360-990-4318 (or by email to [tom.schleis@octapharma.com](mailto:tom.schleis@octapharma.com)),

We appreciate your immediate attention to this recall and sincerely regret any difficulty caused by this action. Octapharma is committed to resolving this issue as quickly as possible.

Sincerely

Judi Miller  
Vice President Medical Affairs  
Octapharma USA Inc.  
5885 Trinity Parkway, Suite 2350  
Centreville VA

Tel: 703-766-4860  
Fax: 703-766-4861

PLEASE COMPLETE & RETURN BY FAX TO OCTAPHARMA  
USA's DRUG SAFETY UNIT

Fax N° 703-766-4861

Voluntary Withdrawal of Octagam® (immune globulin intravenous [human] 5%)

Re: Lot #A732B8431 Exp: 08/09

NAME -----

INSTITUTION -----

ADDRESS -----

-----

-----

Tel -----

email -----

N° of vials purchased -----

N° of vials used -----

N° of vials returned -----