July 28, 2017

URGENT: Octapharma issues voluntary market withdrawal on 1 lot of Octagam® [Immune Globulin Intravenous (human)] 5% liquid preparation

Dear ASD Healthcare Customer:

Octapharma USA Inc., is initiating a voluntary market withdrawal of one lot of Octagam® [Immune Globulin Intravenous (human)] 5% Liquid Preparation, in the interest of public safety. This market withdrawal is being performed as a result of an increased number of reports of hypersensitivity events. All cases resolved without serious injury.

Although there have been no reports of serious injury at this time, Octapharma has determined, through consultation with the public health authorities at the FDA, the most prudent course of action is to suspend further administration of this Octagam® from this production lot.

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 are listed in all manufacturer package inserts. A copy of the Octagam® package insert is attached to this notice.

Octapharma provided the following affected lot information:

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Lot Number</th>
<th>Expiry Dates</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Octagam® 5% 10g 200 mL VL</td>
<td>K720E8441</td>
<td>05/18/2019</td>
<td>68982-0840-04</td>
</tr>
</tbody>
</table>

We ask for your cooperation in taking the following action:

- Immediately quarantine inventory of the affected product.
- Go online to https://www.asdhealthcare.com/requestareturn, log in to your account and complete the return request form.
- Returned vials can be returned in an ambient condition. Customers who return unbroken vials will receive credit.

Affected ASD Healthcare customers who have questions should call ASD Customer Service at 1.800.746.6273 Monday through Friday, 7:30 a.m. to 5:00 p.m. CST.

For the full inventory hold notice please view the attached documents in the following pages.
URGENT - Voluntary market withdrawal – July 26, 2017
octagam® [Immune Globulin Intravenous (human)] 5% Liquid Preparation
Lot Number K720E8441

Dear Distributor Partner:

As a recipient of product from Lot Number K720E8441, please be advised of the following. On July 26, 2017, in the interest of patient safety, Octapharma USA Inc. initiated a voluntary market withdrawal of one lot of octagam® [Immune Globulin Intravenous (human)] 5% 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® 5% [Immune Globulin Intravenous (human)] 5% Liquid Preparation] that is labeled with lot number K720E8441. Although there have been no reports of serious injury at this time, 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 this production lot.

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 are listed in all manufacturer package inserts. A copy of the Octagam® package insert is enclosed.

Distributors that received octagam® 5% directly from Octapharma are asked to immediately quarantine this lot and contact Octapharma’s Customer Service Department at 201 604 1113 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,

Huub Kreuwal
VP, Scientific and Medical Affairs
Octapharma USA, Inc.
121 River Street
Suite 1201
Hoboken, NJ 07030

Customer Service Department
usccustomerservice@octapharma.com
Phone: 866 766-4860
Fax: 201 604-1141

Local Drug Safety Officer
Dipen Patel
dipen.patel@octapharma.com
Phone: 201 604 1137
Fax: 201 604 1141

Octapharma USA, Inc.
Waterfront Corporate Center
121 River Street, 12th Floor
Hoboken, NJ 07030
USA

Phone: (201) 604-1130
Fax: (201) 604-1131
www.octapharma.com/usa
INDICATIONS AND USAGE

Octagam is a plasma-globulin fraction for intravenous administration. It is a 5% solution of human globulin containing a broad spectrum of immunoglobulins (IgG, IgM, and IgA) and has a mean globulin concentration of 50 g/L. Octagam is indicated as replacement therapy in patients with primary immunodeficiencies, as well as for the induction of immune tolerance in patients at risk of developing organ graft rejection. Octagam is also indicated for the treatment of conditions such as acute and chronic immune thrombocytopenia, hereditary angioedema, and other immune-mediated disorders. Octagam is contraindicated in patients with a history of anaphylactic or severe hypersensitivity reactions to the product or its components.

CONTRAINDICATIONS

Octagam is contraindicated in patients with a history of anaphylactic or severe hypersensitivity reactions to the product or its components. Octagam is also contraindicated in patients with a history of hyponatremia or hyperviscosity, or who have been diagnosed with thrombosis, renal dysfunction, or acute renal failure.

WARNINGS AND PRECAUTIONS

1. Hypersensitivity reactions: Octagam may cause hypersensitivity reactions in patients with primary immune deficiencies. These reactions may be severe and may require treatment with antihistamines and corticosteroids. If a patient experiences a severe allergic reaction, Octagam should be discontinued and appropriate supportive measures taken.

2. Thrombosis: Octagam may cause thrombosis in patients with primary immune deficiencies. Thrombosis may be severe and may require treatment with anticoagulants or thrombolytic agents. If a patient experiences symptoms of thrombosis, Octagam should be discontinued and appropriate supportive measures taken.

3. Renal dysfunction: Octagam may cause renal dysfunction in patients with primary immune deficiencies. Renal dysfunction may be severe and may require treatment with supportive measures. If a patient experiences symptoms of renal dysfunction, Octagam should be discontinued and appropriate supportive measures taken.

4. Hypotension: Octagam may cause hypotension in patients with primary immune deficiencies. Hypotension may be severe and may require treatment with supportive measures. If a patient experiences symptoms of hypotension, Octagam should be discontinued and appropriate supportive measures taken.

5. Transfusion-related acute lung injury (TRALI): Octagam may cause TRALI in patients with primary immune deficiencies. TRALI may be severe and may require treatment with supportive measures. If a patient experiences symptoms of TRALI, Octagam should be discontinued and appropriate supportive measures taken.

6. Aseptic meningitis syndrome: Octagam may cause aseptic meningitis syndrome in patients with primary immune deficiencies. Aseptic meningitis syndrome may be severe and may require treatment with supportive measures. If a patient experiences symptoms of aseptic meningitis syndrome, Octagam should be discontinued and appropriate supportive measures taken.
11.1 Composition

The composition of Octagam 5% liquid is shown in Table 8 as follows:

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Immunoglobulin G</td>
<td>900 mg</td>
</tr>
<tr>
<td>pH</td>
<td>4.2 to 4.5</td>
</tr>
</tbody>
</table>

12. REFERENCES

A detailed bibliography is provided at the back of this insert.

13. CONTACT INFORMATION

Inform patients that Octagam 5% liquid is made from human plasma and may contain infectious agents that may cause disease in immunocompromised patients.

Instruct patients to report any adverse reactions to their physician or to the manufacturer of Octagam 5% liquid.

Instruct patients to report any adverse reactions to their physician or to the manufacturer of Octagam 5% liquid.

Table 7: Summary of Secondary Efficacy Variables

<table>
<thead>
<tr>
<th>Study</th>
<th>Sector</th>
<th>Treatment</th>
<th>N</th>
<th>Value (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OCTA-06</td>
<td>Efficacy</td>
<td>Octagam 5% liquid</td>
<td>100</td>
<td>0.05 infections/patient/year (0.05 - 0.08)</td>
</tr>
<tr>
<td></td>
<td>Efficacy</td>
<td>Placebo</td>
<td>100</td>
<td>0.05 infections/patient/year (0.04 - 0.07)</td>
</tr>
</tbody>
</table>

The table shows the number of infections per patient per year for the study OCTA-06, comparing Octagam 5% liquid to placebo. The data indicates a significant reduction in the number of infections in patients treated with Octagam 5% liquid compared to those treated with placebo.