Generic Name:
Immune globulin intravenous (human)
Trade Name:
Octagam
Company:
Octapharma
Notes:

FDA has authorized the market return of Octagam 5 percent after the product was voluntarily withdrawn from the market by the manufacturer in August 2010 because of an observed increase in thromboembolic events (TEEs), according to a news release from Octapharma. For those TEE cases involving Octagam, the root cause was determined to be associated with activated Factor XI, one of the many coagulation factors involved in the complex clotting cascade.

Over the past year, the manufacturer has collaborated with FDA to develop and validate a scientific method to measure the amount of activated Factor XI in its product and made changes to its manufacturing process to utilize a commercial absorbent early in the manufacturing process that minimizes the presence of Factor XI. A quality control test will now occur on every batch of the product and the manufacturer will implement postmarketing studies to ensure product safety.

The product is expected to be available in the coming weeks.

Medication Monitor Categories:
Supplemental Approvals
Use:

Treatment of immune system disorders