

Octapharma – Withdrawal of Octagam[®] [immune globulin intravenous (human) 10% liquid preparation]

 On October 16, 2017, Octapharma announced a voluntary, user-level market withdrawal of one lot of Octagam [immune globulin intravenous (human) 10% liquid preparation] due to an increased number of reports of hypersensitivity events.

Product Description	NDC #	Lot #
Octagam [immune globulin intravenous (human) 10% liquid preparation]	68982-0850-04	K725A8541

- Octagam 10% is indicated in chronic immune thrombocytopenic purpura to rapidly raise platelet counts to control or prevent bleeding in adults.
- Hypersensitivity reactions, including hives and itching, 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.
- Although there have been no reports of serious injury at this time, Octapharma has determined, through consultation with the FDA, the most prudent course of action is to suspend further administration of Octagam 10% from this particular lot.
- Anyone with an existing inventory of the withdrawn Octagam lot should stop use and distribution, and contact Octapharma at **1-866-766-4860** for return information.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using Octagam 10% liquid preparation.



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