CSL Behring

1020 First Avenue, PO Box 61501
King of Prussia, PA
19406-0901

CSL.com
CSLBehring.com

VOLUNTARY PRODUCT LOT WITHDRAWAL

Privigen® 10% Immune Globulin Intravenous (Human)				
The lots affected by this voluntary withdrawal are:				
Date of Withdrawal	**Lot Number**	**Expiration Date**	**NDC Number**	**Size**
October 6, 2021	P100287723	17-NOV-2023	44206-0437-10	10 g/100 mL
October 19, 2021	P100349929	14-JUN-2024	44206-0439-40	40 g/400 mL
December 30, 2021	P100356115	5-JUL-2024	44206-0438-20	20 g/200 mL
January 10, 2022	P100366291	19-AUG-2024	44206-0439-40	40 g/400 mL
	P100371288	20-AUG-2024	44206-0439-40	40 g/400 mL
	P100287718	15-NOV-2023	44206-0436-05	5 g/50 mL

CSL Behring has instituted voluntary withdrawal of certain product lots of Privigen in the US due to an increased frequency of reports of hypersensitivity reactions during or after administration. Hypersensitivity reactions are a known risk with Intravenous Immune Globulin (IVIg) products. This is a precautionary measure that affects only the product lots listed above. These product lot withdrawals are being conducted with the knowledge of the U.S. Food and Drug Administration.

If you have any Privigen vials, please check the lot number and expiration date on the box or vial. If you have any vials from the affected lots, please contact your pharmacy for further instructions on how to return the product.

If you have additional questions regarding the affected lots of Privigen, please contact CSL Behring Medical Information at **1-800-504-5434** or email **MedInfoNA@cslbehring.com.**

Adverse reactions (side effects) or quality problems experienced with the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax:

- Complete and submit the report online: **www.fda.gov/medwatch/report.htm**
- Regular mail or fax: Download form **www.fda.gov/MedWatch/getforms.htm** or call **1-800-332-1088** to request a reporting form, then complete and return to the address on the preaddressed form, or submit by fax to **1-800-FDA-0178**

Adverse events may also be reported to CSL Behring's Adverse Event Reporting line by calling **1-866-915-6958** or by emailing **adverse.events.global@cslbehring.com.**

Our commitment to patient care continues to be a key priority and our guiding principle. We remain dedicated to fulfilling our promise to patients, and to delivering high-quality, lifesaving therapies that improve the lives and wellbeing of patients with rare and serious diseases.

We thank you for your understanding and cooperation.

Debra Bensen-Kennedy, MD
VP Medical Affairs, CSL Behring