CSL Behring

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VOLUNTARY PRODUCT LOT WITHDRAWAL

Hizentra® 20% Immune Globulin Subcutaneous (Human)				
The vial lots affected by this voluntary withdrawal are:				
Date of Withdrawal	Lot Number	Expiration Date	NDC Number	Size
April 13, 2021	P100287881	25-May-2023	44206-0455-10	10 g/50 mL
October 27, 2021	P100340460	12-Nov-2023	44206-0455-10	10 g/50 mL
December 30, 2021	P100343632	24-Nov-2023	44206-0455-10	10 g/50 mL
January 10, 2022	P100369102	16-Feb-2024	44206-0455-10	10 g/50 mL
	P100369103	18-Feb-2024	44206-0455-10	10 g/50 mL

CSL Behring has instituted voluntary withdrawal of certain product lots of Hizentra in the US due to an increase in reported injection-site reactions and hypersensitivity events after administration. 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.

At this time, the cause of this increase in reactions associated with the withdrawn lots of Hizentra is unknown. An investigation is ongoing. The most commonly reported reactions include itching, redness, swelling, and welts around the injection site. The potential safety risk to patients is considered to be low.

If you have any Hizentra 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 Hizentra, 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