

URGENT DRUG WITHDRAWAL

August 6, 2021

This is to inform you that Grifols Therapeutics is initiating a voluntary withdrawal of Gamunex® -C 10% lots, as detailed below.

As a precautionary measure, this voluntary withdrawal is being conducted due to risk of higher rates of allergic/hypersensitivity type reactions, some of which may be medically significant. Hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with IVIG products.

This withdrawal is being conducted with the knowledge of the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research.

Gamunex® -C 10%, lots affected by this withdrawal are listed below:

Lot Number	Material Number	Expiration Date	Market Release	NDC Number
A1GKF00022	729687	19 JAN 2024	26 FEB 2021	13533-800-71
A1GKF00032	729687	21 JAN 2024	03 MAR 2021	13533-800-71
A1GKF00042	729687	23 JAN 2024	04 MAR 2021	13533-800-71
A4GKE01012	729687	02 OCT 2023	12 NOV 2020	13533-800-71
A4GKE01092	729687	28 OCT 2023	08 DEC 2020	13533-800-71
A3GLE01432	729688	10 OCT 2023	16 NOV 2020	13533-800-24
A4GLE01512	729688	30 OCT 2023	22 DEC 2020	13533-800-24
A1GLE01582	729688	13 NOV 2023	23 DEC 2020	13533-800-24
A1GLE01642	729688	06 DEC 2023	22 JAN 2021	13533-800-24

The withdrawal is required to be conducted to the consumer /user level. Please notify your subsidiary customers of this withdrawal and instruct them to return product as noted below.

Please examine your stock immediately to determine if you have any of the above-mentioned lots on hand. If you have product from these lots, cease use of the product immediately. If you have further distributed the product, you must immediately send notification of this withdrawal to your customers. These lots were distributed within the United States only. **Return product to the authorized distributor of record for these lots.** Distributors should return product to Grifols Therapeutics, 8368 US Hwy Bus 70 West, Clayton, NC 27520. For any questions concerning return of the product, contact US Customer Service at (800) 243-4153.

After receipt of returned product by Grifols, you will be credited by your distributor for the returned goods. If you have any technical or clinical questions, please contact US Clinical Communications at (800) 520-2807. Your prompt attention to this notice is appreciated.

Sincerely,



Clark Zervos
Vice President, Quality
Grifols Therapeutics