ASD Healthcare
AmerisourceBergen

M-F 7:00AM to 6:00PM CST
asdhealthcare.com
800.746.6273
800.547.9413

March 11, 2019

Urgent: Grifols Therapeutics Initiates a Voluntary Withdrawal of One Lot of Gamunex® -C 10%

Dear ASD Healthcare Customer:

Grifols Therapeutics is initiating a voluntary withdrawal of one lot of Gamunex® -C 10%. The affected lot information is detailed below.

Please note this lot was never received by ASD Healthcare. In case the product was purchased elsewhere, please be aware of this withdrawal notice.

As a precautionary measure, this voluntary withdrawal is being conducted due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered medically significant. Hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with IVIG products.

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

Grifols provided the following affected lot information for Gamunex® -C 10%:

Lot Number	Material Number	Exp. Date	Market Release	NDC Number
A1GLC01372	729688	02 NOV 2021	15 DEC 2018	13533-800-24

Please examine your stock immediately to determine if you have any of the above mentioned lot on hand. If you have product from this lot, cease use of the product immediately. If you have further distributed the product, you must immediately send notification of this withdrawal to your customers. This lot was distributed within the United States only. **US Distributors and Customers should send return documentation to the Withdrawal Coordinator. Return products to the Warehouse Supervisor. Names and addresses are noted below.**

Jennifer Guy
Withdrawal Coordinator
Grifols Therapeutics
8368 US Hwy Bus 70 West
Clayton, NC 27520
Jennifer.guy@grifols.com

Warehouse Supervisor
Grifols Therapeutics
8368 US Hwy Bus 70 West
Clayton, NC 27520

You will be credited for returned goods and the associated shipping charges. If you have any technical or clinical questions, please contact Grifols US Clinical Communications at (800) 520-2807. If you have inventory that needs replacement, Grifols US Customer Service can be contacted at (800) 243-4153. Your prompt attention to this notice is appreciated.

For the full recall notice, please view the attached document on the following page.

GRIFOLS

Grifols Therapeutics LLC
8368 US 70 Bus Hwy W
Clayton, NC 27520
USA
Tel. 919 553 5011
www.grifols.com

URGENT DRUG WITHDRAWAL

February 21, 2019

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

As a precautionary measure, this voluntary withdrawal is being conducted due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered 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%, lot affected by this withdrawal is:

Lot Number	Material Number	Exp. Date	Market Release	NDC Number
A1GLC01372	729688	02 NOV 2021	15 DEC 2018	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 lot on hand. If you have product from this lot, cease use of the product immediately. If you have further distributed the product, you must immediately send notification of this withdrawal to your customers. This lot was distributed within the United States only. **US Distributors and Customers should send return documentation to the Withdrawal Coordinator. Return product to the Warehouse Supervisor. Names and addresses are noted below.**

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Sincerely,

Lisa Musmanno
Sr. Director, Quality Assurance
Grifols Therapeutics