



## VOLUNTARY MARKET WITHDRAWAL

October 20, 2020

### ZOSYN® (Piperacillin and Tazobactam Injection)

Carton NDC Number	Galaxy Bag Container NDC Number	Lot Numbers	Expiration Date	Strength	Configuration/Count
0206-8862-02	0206-8862-01	LN123822	11FEB21	4.5g 100mL Iso-osmotic Single Dose Galaxy Containers	12 units per case
		LN123877	13FEB21		

Dear Customer:

Pfizer Inc is voluntarily withdrawing the above listed lots of **ZOSYN® (Piperacillin and Tazobactam Injection) 4.5g 100mL Iso-osmotic Single Dose Galaxy Containers to the Hospital/Institution Level.**

Pfizer's decision is based on a review of safety information regarding reported severe and acute adverse events during IV administration which included sudden anaphylactic-type reactions (anaphylactoid reaction) including signs such as dyspnea, hypotension, pulselessness, foaming at the mouth, angioedema and rash. The affected patients had no known allergy to the beta-lactams and had received previous courses of piperacillin/tazobactam. From the investigation to date, there is no indication of a product quality issue and the two lots in scope have been confirmed to meet all product specifications.

This withdrawal decision is made as a precaution while Pfizer continues its investigation into the reported adverse events.

**PFIZER REQUESTS THAT YOU RESPOND TO THIS WITHDRAWAL NOTIFICATION, EVEN IF YOU DO NOT HAVE THE ABOVE LISTED PRODUCT. TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ENCLOSED POSTAGE-PAID, BUSINESS REPLY CARD (BRC) AND RETURN IT TO US, AS DIRECTED, WITHIN FIVE (5) BUSINESS DAYS.** If you have any questions about responding to this letter, please contact Stericycle Inc. at 800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

Our records indicate that you may have received shipment of one or more of the affected lots between August 2020 through September 2020. Please check your stock immediately against the table above. If you have any of the affected product in your inventory, please stop distribution immediately and promptly return it to Stericycle Inc.; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 8143 using the enclosed pre-paid UPS label.



If you received this notification without the prepaid UPS label and BRC, require additional shipping labels, or have questions regarding the return procedure, please contact Stericycle Inc. at 800-805-3093.

If you have further distributed any of these lots to other accounts, please conduct a sub-withdrawal to those accounts and communicate this market withdrawal information immediately. Please request that they immediately cease distribution of the affected lots and promptly return the product directly to the above Stericycle Inc. address. Your accounts do not need to fill out a BRC; however, if they have inventory of the affected product, they can contact Stericycle Inc. at 1-800-805-3093 to obtain pre-paid shipping labels for product returns. Further authorization is not required for product returns.

Hospitals/Institutions/Physicians and Healthcare Providers with existing inventory of the lots which are being withdrawn, should stop use and distribution and quarantine immediately as well as inform all other Healthcare Professionals in their organization as appropriate. Hospitals or retailers that have further distributed the affected product should notify any accounts or additional locations which may have received the affected product from them. Please contact Stericycle at 800-805-3093 for return instructions.

Reimbursement for the returned product will be made by credit memorandum. If you have questions regarding the reimbursement, please contact your Pfizer Customer Service Representative at 800-666-7248 (Mon.-Fri. 8 am-8 pm ET)

This withdrawal is being conducted with the knowledge of the U.S. Food and Drug Administration. We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience this action may cause you.

Healthcare Professionals with questions regarding this withdrawal can contact Pfizer using the below information.

<b>Contact</b>	<b>Contact Information</b>	<b>Areas of Support</b>
Pfizer Medical Information	800-438-1985, option 3 (9am to 5pm ET Monday through Friday)	For medical questions regarding the product
Pfizer Safety	800-438-1985, option 1 (24 hours a day 7 days per week)	To report adverse events or product complaints

Sincerely,

Navin Katyal  
Regional President, North America  
Hospital Business Unit



# ZOSYN 4.5g 100mL Iso-osmotic Single Dose Galaxy Containers

