



# URGENT: DRUG RECALL

March 15, 2019

## Cleocin Phosphate® clindamycin injection, USP

Vial NDC	Carton NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0009-3124-01	0009-3124-03	T78191	04/2019	600 mg/4 mL	Carton containing 25 x 4 mL Single Dose ADD-Vantage® Vials
0009-3447-01	0009-3447-03	T78193	04/2019	900 mg/6 mL	Carton containing 25 x 6 mL Single Dose ADD-Vantage® Vials
0009-6582-02	0009-6582-01	T97469	07/2019	300 mg/2 mL	Carton containing 25 x 2 mL Single Dose ADD-Vantage® Vials
0009-3124-01	0009-3124-03	T97494	07/2019	600 mg/4 mL	Carton containing 25 x 4 mL Single Dose ADD-Vantage® Vials
0009-6582-02	0009-6582-01	W28574	09/2019	300 mg/2 mL	Carton containing 25 x 2 mL Single Dose ADD-Vantage® Vials

Dear Customer:

Pfizer Inc (Pfizer) is voluntarily recalling the above referenced lots of **Cleocin Phosphate® clindamycin injection, USP**. Pfizer initiated this recall because product from these lots does not meet the specification for several specified impurities. Pfizer completed a Health Hazard Assessment, which concluded that the use of the impacted product has an unlikely probability of being associated with adverse events such as abdominal pain, nausea and vomiting, abnormal LFT, and maculopapular rash, and severe adverse events such as diarrhea (including PMC and CDAD). The potential risk to a patient arising from this issue is considered to be low.

**FEDERAL REGULATION 21 CFR 7.49 (d) RESPONSIBILITY OF RECIPIENT STATES: "CONSIGNEES THAT RECEIVE A RECALL COMMUNICATION SHOULD IMMEDIATELY CARRY OUT THE INSTRUCTIONS SET FORTH BY THE RECALLING FIRM ..." PFIZER RECOMMENDS THAT YOU RESPOND TO THIS RECALL EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT. TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ENCLOSED BUSINESS REPLY CARD (BRC) AND RETURN IT, 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).

The recall of the above referenced lots of **Cleocin Phosphate® clindamycin injection, USP** is being conducted to the **Hospital/Institution level**.

Our records indicate that you may have received shipment of the affected lots, which were distributed from November 2017 to May 2018. 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 4834 using the enclosed pre-paid UPS label. **All returns are requested to be completed within six months of this notice date.** 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 wholesale or hospital/institution level accounts, please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request your accounts to 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 800-805-3093 to obtain pre-paid shipping labels for product returns. Further authorization is not required for product returns.

Reimbursement for the returned product will be made by credit memorandum. If you have any questions regarding the reimbursement, please contact your Pfizer Customer Service Representative at 800-533-4535 (Mon.-Fri. 8 am-5:30 pm ET).

This recall 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. If you have any medical questions regarding the product, please contact Pfizer Medical Information at 800-438-1985 (Mon.-Fri. 8 am-7 pm ET).

Sincerely,

A handwritten signature in black ink, appearing to read "Navin Katyal".

Navin Katyal  
General Manager  
Pfizer U.S. Hospital Business