December 03, 2021

URGENT: Important Drug Information

Subject: Printing defects on vial labels of specific lots of Propofol Injectable Emulsion, USP 1000 mg/100 mL (10 mg/mL) containing EDTA

Dear Customer,

Pfizer Inc. is issuing this **Important Drug Information** to alert Health Care Providers (HCPs) that printing defects may be present for lot numbers and expiration dates on the vial labels of specific U.S. lots of **Propofol Injectable Emulsion, USP, 1000 mg/100 mL (10 mg/mL)**. This letter applies to product containing EDTA. The defects appear as partially printed lot numbers and/or expiration dates on the vial labels. The vial cartons are not affected by these printing defects.

Please refer to the table on page 3 for a complete listing of affected product lots, along with corresponding accurate expiration dates.

It is important to note that the printing defects do not necessitate returning the affected product lots.

For Wholesalers/Distributors, if you have further distributed the affected product lots to any other accounts, please communicate this information to those accounts immediately. HCPs are advised to check the table on page 3 to ensure the expiration date on the product labeling is within expiration at the time of use.

Please see the Full Prescribing Information at **http://labeling.pfizer.com/ShowLabeling.aspx?id=15589**.

Please contact Pfizer Customer Service at 844-646-4398 (Mon.-Fri. 8 am-7 pm ET) or your Pfizer representative for any questions you may have regarding this Important Drug Information letter.

If you have any medical questions regarding the product, please contact Pfizer Medical Information at 800-438-1985 (Mon.-Fri. 9 am-5 pm ET).

Adverse events or quality problems experienced with the use of this product may be reported to the U.S. Food and Drug Administration's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- Complete and submit a report online: www.fda.gov/medwatch/report.htm.
- Regular mail or fax: download a reporting form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form. Complete the form and return it to the specified address on the form, or submit the form by fax to 800-FDA-0178 (800-332-0178).

This **Important Drug Information** letter is being issued with the knowledge of the U.S. Food and Drug Administration. We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience this issue may cause you.

Sincerely,

Masum Hossain
Regional President
North America, Hospital Business Unit

Affected Propofol Injectable Emulsion, USP, Product Lots

Carton NDC	Vial NDC	Strength	Configuration/Count	Lot Number	Expiration Date
0069-0248-10	0069-0248-01	1000 mg/100 mL (10 mg/mL)	Carton of 10 x 100 mL Single Patient Use Vials	21L074	05/2023
				21L075	05/2023
				21L076	05/2023
				21L079	05/2023
				21L080	05/2023
				21L081	05/2023
				21L082	05/2023
				21L083	05/2023
				21L084	05/2023
				21L085	05/2023
				21L086	05/2023
				21L087	05/2023
				21L088	05/2023
				21L090	05/2023
				21L091	05/2023
				21L092	05/2023
				21L093	05/2023
				21L094	05/2023
				21L095	05/2023
				21L096	05/2023
				21L097	05/2023
				21L101	06/2023

Examples of Variable Data Vial Label Printing Defects (Expiration Date & Lot Number) for Propofol Injectable Emulsion, USP