

TYPE I DRUG RECALL
URGENT **2nd Notification**



Pfizer Canada Inc.
17300 Trans-Canada Highway
Kirkland, Quebec H9J 2M5

Date: June 21, 2017

Subject: ****2nd Notification** Sodium Bicarbonate Injection USP (8.4% - 1 mEq/mL) 25 x 50 mL vial**
DIN: 00261998
LOT# 72119EV & 72120EV
EXP.: 12/2018 & 12/2018

Pfizer Canada is voluntarily recalling two lots of Sodium Bicarbonate Injection USP (8.4% - 1 mEq/mL) in the 25 x 50 mL vial: Lot 72119EV and lot 72120EV, both with expiry date of 12/2018. These lots were distributed in Canada from February to June 2017.

The classification of this recall is Type I: a situation in which there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death.

This voluntary recall is being conducted following a media fill failure on the aseptic filling line used to manufacture these lots. During the media fill challenge, evidence of a low level of microbial growth was observed. The likelihood of patient exposure to the microorganisms is considered to be low; however Pfizer is recalling these lots out of an abundance of caution.

Please stop the sale and distribution of these lots immediately.

Please conduct an assessment of inventory and **immediately send the attached completed product recall return form to PTM by fax at 1-888-780-4268, even if you do not have any recalled stock on hand.** In this case, check the box to this effect on the form. Your response is vital to Pfizer Canada's ability to monitor the effectiveness of this voluntary recall. Health Canada has been contacted concerning this recall. Your immediate attention to the above instructions is required.

Wholesalers: This product is being recalled at the retailer level. Please forward this notification to all of your customers.

Please return the attached form by June 25, 2017, even if you do not have recalled stock on-hand.

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience that may have been caused by this action. If you have an inquiry of a medical nature related to Sodium Bicarbonate, please contact our Medical Information Group at 1-800-463-6001. For questions relating to the return process, please contact our Customer Service team at 1-800-387-4974.

Sincerely,

A handwritten signature in blue ink, appearing to read "M. Frohloff".

Melissa Frohloff
Team Leader, Quality (AQO)

Enclosure



URGENT - PRODUCT RECALL RETURN FORM

Sodium Bicarbonate Injection USP (8.4% - 1 mEq/mL) 25 x 50 mL vial

Return by fax to PTM at: 1-888-780-4268

(You must return form whether you have inventory of these lots or not)

PLEASE INDICATE BELOW ALL REMAINING VIALS YOU HAVE LEFT IN INVENTORY OF THE RECALLED LOT.

DIN	PRODUCT CODE	PRODUCT DESCRIPTION	FORMAT	SIZE	PACK UPC	VIAL UPC	LOT #	EXPIRY DATE	FIRST SALE OF LOT	# OF VIALS RETURNED
00261998	06625050	Sodium Bicarbonate Injection USP (8.4% - 1 mEq/mL) 25 x 50 mL vial	50mL vial	25-pack	1882135 6625001	0882135 6625004	72119EV	12/2018	Jan 2017	
00261998	06625050	Sodium Bicarbonate Injection USP (8.4% - 1 mEq/mL) 25 x 50 mL vial	50mL vial	25-pack	1882135 6625001	0882135 6625004	72120EV	12/2018	Mar 2017	

We do not have any stock of the above lot

PLEASE COMPLETE THE FORM AND FAX IT WITHOUT DELAY

Customer Name:		
Street Address:		
City:		
Province:		
Postal Code:		
Name of Authorised Person	Signature	Date

Please note that retail and hospital pharmacies should return recalled inventory via the wholesaler through which they currently acquire this product. If you are a pharmacy, please return all units of product identified above as well as a copy of this form to your wholesaler (this includes CPDN). Hospitals that purchase through CPDN and returning affected product to them may use the following Purolator collect number: 0372712 and include the reference number PC061317 on the waybill.

If you are a wholesaler, please return affected product and a copy of this form by Purolator Collect (7983131) to the address below and include the reference number PC061317 on the waybill. Wholesalers and retail pharmacies will be credited by Pfizer Canada at the current provincial list price and hospitals will be credited the price at which they acquired the product.

Med-Turn International Inc (Inmar Healthcare Network)
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