

June 12, 2018

URGENT: Grifols issues a voluntary recall for 1 lot of Profilnine

Dear ASD Healthcare Customer:

Grifols Biologicals is initiating a voluntary product recall of one lot of Profilnine. The lot was packaged with a vial of 5 mL diluent instead of a vial of 10 mL diluent. Grifols Biologicals has determined there is low risk to the patient associated with this issue; however, Grifols Biologicals is requesting the lot to be returned out of caution.

Grifols provided the following affected lot information:

Product Description	Lot Number	Expiry Dates	NDC
Profilnine 1000 IU	A1PBB00072	Jan. 31, 2020	68516-3208-2

We ask for your cooperation in taking the following action:

- Immediately quarantine inventory of the affected product.
- Return affected lots to ASD Healthcare. Begin the returns process by utilizing [Request a Return](#) or call Customer Service at 800.746.6273.

Please contact ASD Healthcare Customer Service at 800.746.6273 with any questions.

For the full recall notice, please view the attached documents in the following pages.

GRIFOLS

URGENT DRUG RECALL

Date: 11 June 2018

Recall No: Profilnine-18-017

To: Richard Taylor

Re: Profilnine 1000IU, NDC 68516-3208-2, LOT A1PBB00072, Expires: 31Jan 20
Date Shipped: 30 May 2018 Quantity Shipped: 100


This notice is to inform you that Grifols Biologicals (GB) is initiating a product recall of a lot of Profilnine. The lot was packaged with a vial of 5 mL diluent instead of a vial of 10mL diluent. GB has determined that there is low risk to the patient associated with this issue; however, GB out of caution, is asking for the lot to be returned. The lot description and the quantity shipped to you are stated above.

- 1) Please check the stock of this lot at your location and create a detailed accounting of the number of vials that have been shipped to customer(s) and the number of vials that are still in your possession. All quantities shipped to your facility should be accounted for.
- 2) For the quantity that is still under your possession, please confirm that you have blocked the lot from further distribution and that they have been placed in Quarantine.
- 3) If you have further distributed the product, you must immediately send notification of this Recall to the accounts where the product was shipped.
- 4) Please confirm that all returned product has been blocked and placed in Quarantine.
- 5) All affected quantities remaining in your facility and/or returned to you will be returned to GB.
- 6) Please provide updates of the recall progress. The update should at a minimum include the number of returned product vials, number of vials consumed, number of vials not returned and reason.
- 7) Please confirm receipt of this notification and provide in an attachment a copy of the detailed accounting mentioned above that the full quantity of the above lot(s) are accounted for and the quantity remaining and/or returned to your site are blocked and in quarantine pending return instructions from GB within 24 hours of the notification time stated below.

Please sign this form confirming receipt of this notification and email it to:

QAC@grifols.com

Subject: Recall - Profilnine-18-01 Attention: Eric Johnston

GB Notification of Customer by: 

Date/time: 23:23 11 Jun 18
(UTC: Coordinated Universal Time)

Customer Confirmation of Receipt of Notification by: _____ Date/time: _____
(UTC: Coordinated Universal Time)