



U.S. Pharmaceuticals  
Pfizer Inc  
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## Pfizer Global Pharmaceuticals

Tom McPhillips  
Vice President, U.S. Trade Group

### URGENT: DRUG RECALL

September 29, 2010

#### Synarel<sup>®</sup> (nafarelin acetate) Nasal Solution

NDC	Lot	Expiration	Strength	Configuration
0025-0166-08	C090734	31-Mar-11	2 mg/mL	8 mL Bottle
0025-0166-08	C091149	31-Jul-11	2 mg/mL	8 mL Bottle

Dear Customer:

Pfizer Inc is recalling the above referenced lots of **Synarel<sup>®</sup> (nafarelin acetate) Nasal Solution**. Pfizer Inc voluntarily initiated this recall when it was determined that a small number of bottles in the above listed lots may have a defective pump assembly which may result in an inaccurate delivery of drug dose. Adverse health consequences with the administration of the above mentioned lots of **Synarel<sup>®</sup> (nafarelin acetate) Nasal Solution** is remote.

**FEDERAL REGULATIONS REQUIRE THAT YOU RESPOND TO THIS RECALL, EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT. TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ENCLOSED POSTAGE-PAID, BUSINESS REPLY CARD AND RETURN IT TO US WITHIN FIVE (5) BUSINESS DAYS. IF YOU HAVE ANY QUESTIONS ABOUT RESPONDING TO THIS LETTER, PLEASE CONTACT STERICYCLE INC AT 1-800-805-3093.**

The recall of **Synarel<sup>®</sup> (nafarelin acetate) Nasal Solution** is being conducted to the **Retail Level**.

Our records indicate that you may have received shipment of the affected lots between October 2009 and August 2010. Please check your stock immediately against the table above. If you have any of the affected lots of product in your inventory, please stop distribution and promptly return them to Stericycle Inc; 2670 Executive Drive; Suite A, Indianapolis, IN 46241 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 1-800-805-3093. If you have any medical inquiries please contact Pfizer Medical Information at 1-800-438-1985.

If you have further distributed these lots to the retail level, please conduct a sub-recall and communicate this recall information to those accounts immediately. Please request that they immediately cease distribution of the affected lots and promptly return the product directly to the above address. If they have inventory of the affected product, they should contact Stericycle Inc. at 1-800-805-3093 to obtain pre-paid shipping labels for product return. Further authorization is not required for product return. 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 1-800-533-4535.

If you received free product through any of the following Pfizer Helpful Answers<sup>®</sup> patient assistance programs: Connection to Care<sup>®</sup>, Sharing the Care<sup>®</sup>, Pfizer Hospital Partnership Program, or a state bulk replenishment program, and have already dispensed product to patients, no action is required. If you have any of this inventory in stock, please follow the instructions above for returning the product to Stericycle. Pfizer Customer Service will replace the returned product with new inventory.

This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience you may have been caused by this action.

Sincerely,

Tom McPhillips