



June 2021

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**Subject: Recall by Genentech limited to 2 lots of Xolair® (omalizumab) Prefilled Syringes 150mg/1mL (NDC 50242-215-01, lot# 3352758 and lot# 3352759)**

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Dear Healthcare Provider:

The purpose of this letter is to inform you about a recall of 2 lots of Xolair Prefilled Syringe (PFS) due to reduced shelf-life.

XOLAIR is an anti-IgE antibody indicated for:

- Moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
- Nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment
- Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment

**Background of the Recall**

Genentech is voluntarily conducting this limited recall because routine testing showed that Xolair PFS from these two lots have a shorter expiration period than expected. To date, no safety issues have been confirmed and no other lots are affected. This recall is precautionary with the knowledge of the U.S. Food and Drug Administration (FDA).

It is possible that a limited number of syringes from these lots are still in circulation. As a precautionary measure, the 2 implicated Xolair PFS lots are being recalled.

**Prescriber Action - Multiple steps may be needed:**

1. Please examine your Xolair PFS inventory immediately to determine if you have remaining inventory of any of the lots listed below. If you do, stop dispensing and administering these lots. No additional action is needed if you administered Xolair from these lots to a patient.

Product Description	NDC	Lot Number	Expiration Date on Box	Distribution Date After
Xolair® (omalizumab) 150mg/1mL PFS	50242-215-01	3352758 3352759	Aug 2021	8/5/2020

2. If you approved a patient for self-injection outside of your office who may 1) have received

Xolair 150mg/1mL PFS after 8/5/2020 AND 2) still have it in their possession, share the enclosed [Dear Patient Letter](#) that will instruct patients on how to return recalled syringes

3. Tell your patients and/or their caregivers to report any suspected adverse reactions and/or product complaints with Xolair immediately.
4. For replacement instructions, see the bottom of this letter.

NOTE: you may also receive a similar recall notification letter through your distributor.

### **Reporting Adverse Events and Product Complaints**

Please report any adverse event suspected to be associated with the use of Xolair to Genentech at (888) 835-2555. Alternatively, this information may be reported to FDA's MedWatch reporting system at (800) FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please report any product complaint suspected to be associated with the use of Xolair to Genentech at (800) 334-0290.

### **Genentech Medical Information**

Should you have any questions about the information in this letter or the safe and effective use of Xolair, please contact us at (800) 821-8590.

This letter is not intended as a complete description of the benefits and risks related to the use of Xolair. Please refer to the enclosed [full prescribing information and medication guide](#).

We are working hard to assist patients and healthcare providers and we appreciate your understanding and cooperation.

Sincerely,



Jamie Freedman MD, PhD  
Head of U.S. Medical Affairs

### **Replacement instructions:**

If you are contacted by a patient for a replacement and the patient:

- Received recalled Xolair PFS through your office that was shipped by an SP:
  - Call the SP who shipped the product and request a replacement.
  - Once a replacement product is shipped to your office, please arrange to provide the replacement product to your patient.
- Received recalled Xolair PFS directly through the SP:
  - Have the patient call the SP who shipped the product and request a replacement

If you have general (buy and bill) inventory of these lots:

- Call Qualanex at **1-888-504-2013** for return instructions. Product must be returned in order to receive a credit through your distributor.

If you have patient-specific inventory of these lots you will need to do 2 things:

1. Call the SP who shipped the product and request a replacement
2. Contact Qualanex at **1-888-504-2013** for instructions on how to return recalled syringes