

June 2021

Subject: Recall by Genentech limited to 2 lots of Xolair® (omalizumab) Prefilled Syringes 150mg/1mL (lot# 3352758 and lot# 3352759)

Your doctor is sharing this letter with you because they decided you are able to give your own XOLAIR prefilled syringe injections, and they believe you may have XOLAIR 150mg/1mL prefilled syringes at your home.

Dear Patient,

We want you to be aware that Genentech is voluntarily doing a limited recall for two lots of Xolair 150mg/1mL prefilled syringes. Routine testing showed that Xolair prefilled syringes from these two lots have a shorter expiration date than what is listed on the packaging box. This recall is precautionary and to date, no safety issues have been confirmed with prefilled syringes from these lots. No other Xolair prefilled syringes are affected. We are taking this precautionary step for patients and we are doing this recall with the knowledge of the U.S. Food and Drug Administration.

If you do not have any Xolair 150mg/1mL prefilled syringes at home, you do not need to do anything. If you previously took Xolair from either lot, there are no confirmed risks and no further action is necessary.

If you do have any Xolair 150mg/1mL prefilled syringes at home, please immediately follow these steps:

- Check the lot number on the box (see the image below).



Product Description	NDC	Lot Number	Expiration Date on Box
Xolair® (omalizumab) 150mg/1mL prefilled syringe	50242-215-01	3352758 3352759	Aug 2021

- If you have a box that has lot number 3352758 or 3352759, please take these 3 steps:
 1. **Do not use** the prefilled syringe.
 2. **Get a replacement:** Contact the pharmacy or doctor's office who gave the Xolair prefilled syringe to you for further instructions on how to receive a replacement free of charge.
 3. **Return your recalled prefilled syringes:** Call Qualanex at **1-888-504-2013** to get instructions on how to return the syringes (7 am to 4 pm Monday to Friday EST).
- If you no longer have the box, you should still call Qualanex at **1-888-504-2013** for instructions.

We understand that you may have concerns or questions.

For questions about your Xolair treatment contact your doctor. You should continue taking your medicine as directed by your doctor; please do not make any changes to your treatment without talking to your doctor.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

For medical information about Xolair, please call Genentech Medical Communications at (800) 821-8590 (8 am to 8 pm Monday to Friday EST).

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

Sincerely,

A handwritten signature in black ink that reads "Jamie Freedman". The signature is written in a cursive, flowing style.

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