

**MEDICATION GUIDE
XOLAIR®
(omalizumab)**

**IMPORTANT: XOLAIR SHOULD ALWAYS BE INJECTED
IN YOUR DOCTOR'S OFFICE.**

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT XOLAIR?

A severe allergic reaction called anaphylaxis has happened in some patients after they received Xolair. Anaphylaxis is a life-threatening condition and can lead to death so get emergency medical treatment right away if symptoms occur.

Signs and Symptoms of anaphylaxis include:

- wheezing, shortness of breath, cough, chest tightness, or trouble breathing
- low blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety, or feeling of “impending doom”
- flushing, itching, hives, or feeling warm
- swelling of the throat or tongue, throat tightness, hoarse voice, or trouble swallowing

Get emergency medical treatment right away if you have signs or symptoms of anaphylaxis after receiving Xolair.

Anaphylaxis from Xolair can happen:

- right after receiving a Xolair injection or hours later
- after any Xolair injection. Anaphylaxis has occurred after the first Xolair injection or after many Xolair injections.

Your healthcare provider should watch you for some time in the office for signs or symptoms of anaphylaxis after injecting Xolair. If you have signs or symptoms of anaphylaxis, tell your healthcare provider right away.

Your healthcare provider should instruct you about getting emergency medical treatment and further medical care if you have signs or symptoms of anaphylaxis after leaving the doctor's office.

WHAT IS XOLAIR?

Xolair is an injectable medicine for patients 12 years of age and older with moderate to severe persistent allergic asthma whose asthma symptoms are not controlled by asthma medicines called inhaled corticosteroids. A skin or blood test is done to see if you have allergic asthma.

WHAT ELSE SHOULD I KNOW ABOUT XOLAIR?

- You should not receive Xolair if you have ever had an allergic reaction to a Xolair injection.

- Do not change or stop taking any of your other asthma medicines unless your healthcare provider tells you to do so.
- There are other possible side effects with Xolair. Talk to your doctor for more information. You can also go to www.xolair.com or call 1-866-4XOLAIR (1-866-496-5247).
- **You may report side effects to FDA at 1-800-FDA-1088.**

This Medication Guide has been approved by the U.S. Food and Drug Administration.

XOLAIR® (omalizumab)

Manufactured by:
Genentech, Inc.
 A Member of the Roche Group
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 South San Francisco, CA 94080-4990

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 LX1331
 4855302

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 A Member of the Roche Group
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 South San Francisco, CA 94080-4990
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 East Hanover, NJ 07936-1080

Part Three: Administering Xolair

Patient Consent Form

Consent to Xolair Administration Program

1. I authorize _____ and his/her medical staff to perform the necessary Xolair injections for myself, a minor child or another person for whom I have authorization to sign.
2. The following information has been discussed with me:
 - a. The nature and purpose of the Xolair treatment program
 - b. The risks of the treatment including the possibility of an allergic reaction as well as the risk that the treatment program may not accomplish the desired objectives
 - c. The possible outcome of the treatment
 - d. The available alternative medical treatments
 - e. The prognosis if the program is not followed
 - f. The need for regular therapy and follow-up including the need to evaluate my asthma by keeping records of my medication use, symptoms and need for unscheduled care. (This may be done by mail-in forms, telephone, computer, pharmacy records or similar means)
3. I have had sufficient opportunity to discuss my condition with my allergist, and all of my questions have been answered to my satisfaction. I have read and understand the Xolair Treatment Information Form. I believe that I have adequate knowledge upon which to base an informed consent to this program.
4. I consent to other diagnostic and therapeutic procedures and the monitoring program that the physician decides might be necessary due to unexpected conditions (such as treatment of an allergic reaction).
5. I am aware that the practice of medicine is not an exact science, and no guarantees have been made to me concerning the results of this program.
6. I have read and fully understand this consent form.

Signature of patient/other

Date signed

If other, relationship to patient

Witness