



PATIENT INFORMATION LETTER: XOLAIR (OMALIZUMAB)

What is Xolair (omalizumab), and why is it being prescribed?

The allergic person makes too much of a certain protein in the body, called IgE antibody. The overproduction of this protein may result in the development of various allergic conditions such as allergic rhinitis (hayfever), allergic asthma, venom sensitivity, food or drug allergy.

Xolair is a drug that acts by binding to the IgE allergic antibody in the blood stream and hence neutralizing (blocking) its actions. The U.S. Food and Drug Administration (FDA) has approved Xolair for the treatment of patients with moderate to severe persistent asthma.

Xolair is indicated for adults and adolescents (≥ 12 years age) who have moderate to severe asthma that is not currently controlled with inhaled corticosteroids and are sensitive (allergic) to perennial (year-round) aeroallergens (for example: dust mites, animals, mold, cockroach, and certain pollens).

Benefit

Xolair has been shown to decrease the number of asthma attacks in patients with more moderate to severe asthma, and in some patients it allows a reduction in, and sometimes complete elimination of, other asthma medications.

How is it administered, how often is it given, and for how long?

Your Xolair dose will be chosen based on your body weight and the results of a blood test that measures your level of IgE. You will receive 1-2 injections of Xolair in your upper arm every 2 to 4 weeks depending on these factors. Unless your weight changes significantly, the dose and injection schedule should not change once your treatment has started.

It may take several months before you begin to notice benefits from Xolair. However, once benefits are observed, they should last for as long as you continue to receive your regular injections. If for some reason your injections are stopped, we would expect the effects to wear off within 6 months to a year. There are no lasting benefits from taking this drug.

What does it cost, and will my insurance cover it?

This is an expensive medication, costing about \$500-\$2000 per month. Because each insurance company has its own rules, we need to request approval from your insurance company before starting therapy. Once approved, you will learn exactly how

much of the cost of these injections will be covered by your insurance and how much you will be required to pay.

What are the risks associated with its administration?

The clinical studies performed for the FDA suggest that Xolair is very safe. So far, more than 2000 adults and adolescents have taken the drug continuously for at least 6 months. The average age of patients receiving Xolair was 42 years, with 134 patients 65 years of age or older; 60% were women, and 85% Caucasian. The overall number of adverse reactions was similar among those patients taking Xolair or placebo (an inactive ingredient). These adverse reactions included injection site reactions (45%), colds (23%), sinus infections (16%), headache (15%), and sore throat (11%).

Serious adverse reactions occurred in less than 1% of patients. The most serious reactions occurring in studies with Xolair were cancers and generalized allergic reactions from receiving the drug.

Cancers

Cancers were seen in one of every 200 Xolair-treated study volunteers [20 of 4127 (0.5%)] compared with one of every 500 control volunteers (patients who did not take the drug in studies of asthma and other allergic disorders [5 of 2236 (0.2%)]. A panel of cancer specialists asked to review this information concluded that there was no evidence to suggest that this drug actually causes cancer. The cancers noted in Xolair-treated volunteers were a variety of types: with breast, skin (non-melanoma), prostate, melanoma, and parotid occurring more than once, and five other types occurring once each. The majority of volunteers were observed for less than 1 year. The impact of longer exposure to Xolair, or use in people at higher risk for cancer (eg: elderly, current smokers), is not known.

Generalized allergic reactions (anaphylaxis) and their treatment

Anaphylaxis was noted to occur within 2 hours of the first or subsequent dose of Xolair in 3 (< 0.1%) study volunteers without other identifiable allergic triggers. These events included hives and throat and/or tongue swelling. At the first sign of a generalized allergic reaction, adrenaline (epinephrine) is usually given to counteract the reaction. Severe reactions that include chest symptoms are treated in the same way that an asthma attack would be treated.

Local reactions and their treatment

Local reactions that consist of swelling of the arm, redness or tenderness at the site of injection are usually handled with simple measures such as local cold compresses or the use of medications such as antihistamines or aspirin.

Where will your injections be administered?

Since the possibility exists that a Xolair injection may cause a generalized allergic reaction, we require that Xolair be administered at our facility. You will be

observed up to 120 minutes after each injection. The period of observation will be determined based on your physician’s instructions. A doctor who can treat severe reactions to the drug will be available in the clinic during the time that you are present in the Center. If a severe allergic reaction to Xolair occurs, you will not receive any additional Xolair treatments.

If you develop a delayed reaction to your Xolair injection (after you leave our facility) please either return to our Center or proceed to the nearest emergency room and then contact us as soon as possible. Before additional injections are given, or for questions or assistance, please call us at 410-550-2300 during usual business hours, or the Johns Hopkins page operator at 410-955-4331 and ask to speak to the allergist-on-call.

Patient reviewed: _____
Name date

Physician reviewed: _____
Name date

Witness: _____
Name date