Allergy Consultants, P.A.

Specialists in Pediatric and Adult Allergy, Asthma, and Sinus Disease

Arthur F. Fost, M.D. • David A. Fost, M.D. • Antonio A. de la Cruz, M.D. • Satya D. Narisety, M.D.

XOLAIR INFORMED CONSENT

What is Xolair?

Xolair is a medication for patients 12 years of age or older with moderate to severe persistent allergic asthma whose asthma symptoms are not well controlled by asthma medicines. A skin or blood test is done to confirm you have allergic asthma. This medication is also used for patients who suffer from chronic urticaria, when medications such as antihistamines have failed to bring relief.

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 old, with 134 patients 65 years old or older; 60% were women, and 85 % Caucasian. The overall number of adverse reactions was similar among patients taking Xolair or placebo. (an inactive ingredient). These adverse reactions included injection site reactions (45 %), colds (23%), sinus infections (16%), headaches (15%) and sore throat (11%).
Serious adverse reactions occurred in less than 1 percent of patients. The most serious reaction occurring in studies with XOLAIR were cancers and generalized allergic reactions from receiving the drug.

Cancers:

Cancers were seen in 20 of 4127(0.5 percent) of Xolair-treated study volunteers compared with 5 of 2236 (0.2 percent) of control volunteers, (Patients who did not take the drug) in studies of asthma and other allergic disorders. 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: breast, skin (non melanoma), prostate, melanoma, and parotid occurring more that once, and five other types occurring once each. The majority of volunteers were observed for less than one year. The impact of longer exposure to
XOLAIR, or use in people at a higher risk for cancer (e.g. 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 (less than 0.1%) study volunteers without other identifiable allergic triggers. These events included hive and throat and/or tongue swelling. At first sign of a generalized allergic reaction, epinephrine is usually given to counteract the reaction.

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 "funny".
*Flushing, itching, hives, or feeling warm anywhere on the body.
*Swelling of throat or tongue, throat tightness, hoarse voice, or trouble

swallowing.
*Nausea, vomiting, diarrhea, stomach cramps, uterine cramps in women.

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

Local reactions and their treatment:

Local reactions that consist of swelling of the arm, redness or tenderness at the site of the injection are usually handled with simple measures such as local cold compresses and/or use of medications such as antihistamines or over the counter hydrocortisone creams may be applied twice daily to the area.

Where will your injection 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 for 2 hours after your first injection. A doctor will be available at the office to treat any adverse reaction. 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 the office) please either return to our office or proceed to the nearest emergency room with someone else driving you and then contact us as soon as possible. Before additional injections are given, or for further questions or assistance, please call us at (973) 857-0330.

Patient signature:_____ _____
Name Date

Physician reviewed:_____ _____
Date

Witness signature: _____ _____
Date

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Consent to Xolair administration program

1. I authorize_____ and his/her medical staff to perform the necessary Xolair injection 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 medications.
   e. The prognosis if the program is not followed.
   f. The need for regular therapy and follow-up including the need to evaluate my condition. For those patients receiving Xolair for asthma it will be required for you to see the M.D. every 4 months. For those receiving Xolair for chronic urticaria it will be required for you to see the M.D. every 6 months.
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 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.

_____ _____

Patient signature Date

_____ _____

Witness signature Date