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Xolair (*omalizumab*)

An overview of Xolair and why it is authorised in the EU

What is Xolair and what is it used for?

Xolair is used to improve the control of severe persistent asthma caused by an allergy. It is used as an add-on to asthma treatment in patients from 6 years of age when an antibody called immunoglobulin E (IgE) causes the asthma. Xolair must only be used in patients who:

- have had a positive skin test result for an allergy caused by an allergen (a stimulus that causes an allergy) in the air, such as house dust mites, pollen or mould;
- have frequent symptoms during the day or waking up during the night;
- have had many severe asthma attacks (that require rescue treatment with other medicines) despite treatment with high doses of inhaled corticosteroids plus a long-acting inhaled beta₂ agonist.

In patients aged 12 years or over, Xolair must only be used if the lung function is less than 80% of normal.

Xolair is also used to treat:

- chronic (long-term) spontaneous urticaria (itchy rash). It is used as an add-on to existing treatment in patients aged 12 years or over in whom treatment with an antihistamine does not work well enough;
- severe chronic rhinosinusitis with nasal polyps (inflamed lining of the nose and sinuses with swellings in the nose) in adults. It is used with a corticosteroid given into the nose when the corticosteroid alone does not work well enough.

Xolair contains the active substance omalizumab.

How is Xolair used?

Xolair can only be obtained with a prescription and treatment should be started by a doctor who has experience of treating the condition for which it is to be used.

It is available in two forms: as a vial containing a powder and solvent that are made up into a solution for injection; and as a prefilled syringe containing a solution for injection. The powder and solvent form must be given by a doctor. The prefilled syringe may be used by the patient or caregiver following training and provided that the patient is not at high risk of a severe allergic reaction to the medicine.



The dose of Xolair and how often it is given depends on the condition being treated. For allergic asthma and chronic rhinosinusitis with nasal polyps, the dose is calculated on the basis of the patient's weight and levels of IgE in the blood.

For more information about using Xolair, see the package leaflet or contact your doctor or pharmacist.

How does Xolair work?

The active substance in Xolair, omalizumab, is a monoclonal antibody, a type of protein, designed to attach to IgE, which is produced in large quantities in patients with allergies and triggers an allergic reaction in response to an allergen. By attaching to IgE, omalizumab 'mops up' the free IgE in the blood. This means that when the body encounters an allergen, there is less IgE available to trigger an allergic reaction. This helps to reduce the symptoms of allergy, such as asthma attacks. IgE is also involved in the inflammatory process, and reducing the amount of IgE shrinks nasal polyps and improves symptoms.

Although the role of IgE in chronic spontaneous urticaria is less clear, reducing its availability with omalizumab may reduce inflammation and improve symptoms.

What benefits of Xolair have been shown in studies?

Allergic asthma

Xolair was studied in over 2,000 patients aged 12 years or over with allergic asthma in five main studies, including one involving 482 patients with severe allergic asthma that was not controlled by conventional treatments. In all the studies, Xolair was compared with placebo (a dummy treatment), when added to the patients' existing treatment. Xolair reduced the number of asthma attacks by around half. Over the first 28 or 52 weeks of treatment in the first three studies, there were around 0.5 asthma attacks per year in the Xolair group and around 1 per year in the placebo group. In addition, fewer of the patients receiving Xolair had asthma attacks than those receiving placebo. Patients treated with Xolair also reported greater improvement in quality of life (assessed using standard questionnaires) and used less fluticasone (a corticosteroid). The effects of Xolair were greater in patients with severe asthma.

In the study with patients with severe allergic asthma, there was no difference in the number of asthma attacks between Xolair and placebo, but Xolair led to a similar reduction in the number of asthma attacks as in previous studies.

In a study in 627 children with allergic asthma aged between 6 and 12 years, the number of asthma attacks was lower in those receiving Xolair. Among the 235 children who were being treated with high doses of inhaled corticosteroids plus a long-acting inhaled beta₂ agonist before the start of the study, there were an average of 0.4 asthma attacks over the first 24 weeks of treatment in those receiving Xolair, compared with 0.6 in those receiving placebo.

Chronic spontaneous urticaria

Xolair was investigated in 3 main studies involving a total of 978 patients with chronic spontaneous urticaria who did not respond to antihistamine-based treatment. In all the studies, Xolair was compared with placebo, when added to the patients' existing treatment. The main measure of effectiveness was the change in itching severity after 12 weeks of treatment, as measured on a scale ranging from 0 (no itch) to 21 (maximum itch severity). After 12 weeks of treatment, Xolair 300 mg reduced itching by 4.5 to 5.8 points more than placebo. The effects were maintained after 6 months of treatment.

Chronic rhinosinusitis with nasal polyps

Two main studies involving a total of 265 patients showed a benefit from Xolair in chronic rhinosinusitis with nasal polyps not controlled well enough by corticosteroids given into the nose. All patients continued to receive treatment with mometasone (a corticosteroid) applied to the nose combined with either Xolair or placebo. The nasal polyp score (which can range from 0 to 8) improved by 0.99 points after 24 weeks in patients treated with Xolair compared with 0.13 points in patients receiving placebo. The nasal congestion score (which can range from 0 to 3) improved by 0.80 points in patients treated with Xolair compared with 0.28 points in patients receiving placebo.

What are the risks associated with Xolair?

The most common side effects with Xolair (which may affect up to 1 in 10 people) are headache and injection site reactions such as pain, swelling, redness and itching.

The most common side effects in children aged 6 to 12 years with allergic asthma include fever (very common) and upper abdominal (belly) pain.

In patients with chronic spontaneous urticaria the most common side effects also include joint pain, sinusitis and upper respiratory tract infections (nose and throat infections) while those in patients with chronic rhinosinusitis with nasal polyps also include upper abdominal pain, dizziness and joint pain.

For the full list of side effects and restrictions with Xolair, see the package leaflet.

Why is Xolair authorised in the EU?

The European Medicines Agency decided that Xolair's benefits are greater than its risks and it can be authorised for use in the EU.

The Agency concluded that, overall, results from studies in allergic asthma, chronic spontaneous urticaria and chronic rhinosinusitis with nasal polyps showed that Xolair was effective in reducing symptoms of the conditions, but the Agency noted that data on use beyond 6 months are limited for chronic spontaneous urticaria. The side effects of Xolair are manageable.

What measures are being taken to ensure the safe and effective use of Xolair?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Xolair have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Xolair are continuously monitored. Side effects reported with Xolair are carefully evaluated and any necessary action taken to protect patients.

Other information about Xolair

Xolair received a marketing authorisation valid throughout the EU on 25 October 2005.

Further information on Xolair can be found on the Agency's website:
ema.europa.eu/medicines/human/EPAR/Xolair.

This overview was last updated in 08-2020.