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EPAR summary for the public

Xolair

omalizumab

This document is a summary of the European public assessment report (EPAR) for Xolair. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Xolair.

What is Xolair?

Xolair is a medicine that contains the active substance omalizumab. 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. Each vial and syringe contains 75 or 150 mg of omalizumab.

What is Xolair used for?

Xolair is used to improve the control of severe persistent asthma that is caused by an allergy. It is used as an add-on to existing asthma treatment in patients aged six years or over. Xolair treatment should only be considered when the asthma is caused by an antibody called immunoglobulin E (IgE). All patients receiving Xolair must meet the following criteria:

- they must 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;
- they must have frequent symptoms during the day or waking up during the night;
- they must have had many severe 'exacerbations' of asthma (where asthma gets worse, requiring rescue treatment with other medicines) despite treatment with high doses of inhaled corticosteroids plus a long-acting inhaled beta2 agonist.

Patients aged 12 years or over must also have reduced lung function (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 who do not respond to treatment with antihistamines.

The medicine can only be obtained with a prescription.

How is Xolair used?

Xolair treatment should be started by a doctor who has experience in the treatment of severe persistent asthma or chronic spontaneous urticaria.

For the treatment of asthma, Xolair is given by a healthcare professional as an injection under the skin of the shoulder or the thigh every two or four weeks. Before giving Xolair to patients with asthma, the doctor must measure the level of IgE in the patient's blood. Patients with low IgE levels are less likely to benefit from the medicine. The dose of Xolair and how often it is given depend on the level of IgE in the blood and body weight. The usual dose range is between 75 and 600 mg in one to four injections, and the maximum recommended dose is 600 mg every two weeks.

In the treatment of asthma, Xolair is intended for long-term use. It usually takes 12 to 16 weeks for Xolair to show a benefit.

For the treatment of chronic spontaneous urticaria, Xolair is given by a healthcare professional by injection under the skin of the shoulder or the thigh, in a dose of 300 mg every four weeks. The doctor will periodically re-assess the need to continue treatment with Xolair.

How does Xolair work?

The active substance in Xolair, omalizumab, is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen) in the body. Omalizumab has been designed to attach to human 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 circulating 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. Although the role of IgE in chronic spontaneous urticaria is less clear, reducing its availability with omalizumab has been shown to improve the symptoms of this condition.

How has Xolair been studied?

Xolair has been studied in over 2,000 patients aged 12 years or over with allergic asthma in five main studies, including one study involving 482 patients with severe allergic asthma that was not controlled by conventional treatments. It has also been studied in 627 children aged between six and 12 years.

In all of the studies, Xolair was compared with placebo (a dummy treatment), when they were added to the patients' existing treatment. The main measures of effectiveness were the number of exacerbations, the number of patients who had an exacerbation, quality of life (assessed using standard questionnaires), and the amount of inhaled corticosteroid that the patients needed to take to treat their asthma.

Xolair has also been 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 of the studies, Xolair was compared with placebo, when they were 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).

What benefit has Xolair shown during the studies?

In the studies in patients with allergic asthma aged 12 years or over, Xolair reduced the number of exacerbations by around half. Over the first 28 or 52 weeks of treatment in the first three studies, there were around 0.5 exacerbations per year in the Xolair group and around one per year in the placebo group. In addition, fewer of the patients receiving Xolair had exacerbations than those receiving placebo. They also reported a greater improvement in quality of life and used less fluticasone (a corticosteroid). The effects of Xolair were greater in patients with severe asthma.

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

In the study in children with allergic asthma aged between six and 12 years, the number of exacerbations 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 was an average of 0.4 exacerbations over the first 24 weeks of treatment in those receiving Xolair, compared with 0.6 in those receiving placebo.

In the studies in patients with chronic spontaneous urticaria, following 12 weeks of treatment, Xolair 300 mg improved the symptoms of itching by 4.5 to 5.8 points more than placebo. The effects were maintained after 6 months of treatment.

What is the risk associated with Xolair?

In patients with allergic asthma aged 12 years and over, the most common side effects with Xolair (seen in between 1 and 10 patients in 100) are headache and injection site reactions, including swelling, redness, pain and itching. In children aged between six and 12 years, the most common side effects (seen in more than 1 patient in 10) are headache and pyrexia (fever).

In patients with chronic spontaneous urticaria, the most common side effects with Xolair (seen in between 1 and 10 patients in 100) are sinusitis (inflammation of the sinuses), headache, arthralgia (joint pain), injection site reactions and upper respiratory tract infection (colds).

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

Why has Xolair been approved?

The CHMP decided that Xolair's benefits are greater than its risks and recommended that it be given marketing authorisation. The Committee concluded that, overall, there was a pattern of results in the studies of Xolair in asthma that show that the medicine is effective in treating severe allergic asthma. The CHMP also concluded that Xolair (300 mg) was shown to significantly improve the symptoms of chronic spontaneous urticaria when used as add-on to the patients' existing treatment, but noted that study data on long-term use beyond 6 months are limited.

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

A risk management plan has been developed to ensure that Xolair is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the

package leaflet for Xolair, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Xolair:

The European Commission granted a marketing authorisation valid throughout the European Union for Xolair on 25 October 2005.

The full EPAR for Xolair can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Xolair, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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