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Omlyclo (*omalizumab*)

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

What is Omlyclo and what is it used for?

Omlyclo is a medicine 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 the asthma is caused by an antibody called immunoglobulin E (IgE). Omlyclo should only be used in patients who:

- have had a positive skin test result for an allergy caused by an allergen (a substance 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 despite treatment with high doses of inhaled corticosteroids plus a long-acting inhaled beta-2 agonist (other medicines to treat asthma).

In patients aged 12 years or over, Omlyclo should only be used if the patient has reduced lung function (measured as less than 80% of their FEV1, the maximum volume of air they can breathe out in 1 second).

Omlyclo 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 (another medicine to treat urticaria) 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.

Omlyclo contains the active substance omalizumab and is a biological medicine. It is a biosimilar medicine; this means that it is highly similar to another biological medicine (the reference medicine) that is already authorised in the EU. The reference medicine for Omlyclo is Xolair. For more information on biosimilar medicines, see here.

How is Omlyclo used?

Omlyclo can only be obtained with a prescription and treatment should be started by a doctor who is experienced in treating the condition for which it is to be used.

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Omlyclo is available as a prefilled syringe containing a solution for injection under the skin. Patients or their caregivers can inject the medicine once they have received training from a healthcare professional and provided that the patient is not at high risk of a severe allergic reaction to the medicine.

The dose of Omlyclo 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 based on the patient's weight and levels of IgE in the blood.

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

How does Omlyclo work?

The active substance in Omlyclo, omalizumab, is an antibody (a type of protein) designed to attach to IgE, which is produced at high levels in people 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 inflammation. By reducing the amount of IgE in the blood, omalizumab helps to reduce inflammation, thereby helping to shrink nasal polyps and improve symptoms.

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

What benefits of Omlyclo have been shown in studies?

Laboratory studies comparing Omlyclo with Xolair have shown that the active substance in Omlyclo is highly similar to that in Xolair in terms of structure, purity and biological activity. Studies have also shown that giving Omlyclo produces similar levels of the active substance in the body to giving Xolair.

In addition, the effects of Omlyclo and Xolair on itch severity were found to be comparable in a study involving 408 people with chronic spontaneous urticaria who did not respond to antihistamine treatment. After 12 weeks of treatment, the weekly itch severity score was reduced by an average of 9.21 points in people who received Omlyclo compared with an average of 9.98 points in those who received Xolair.

Because Omlyclo is a biosimilar medicine, the studies on effectiveness and safety of omalizumab carried out with Xolair do not all need to be repeated for Omlyclo.

What are the risks associated with Omlyclo?

The safety of Omlyclo has been evaluated and, based on all the studies carried out, the side effects of the medicine are considered to be comparable to those of the reference medicine Xolair.

For the complete list of side effects and restrictions of Omlyclo, see the package leaflet.

In adults with allergic asthma, the most common side effects with Omlyclo (which may affect up to 1 in 10 people) include headache and injection site reactions such as pain, swelling, redness and itching. Additional common side effects in people with chronic rhinosinusitis with nasal polyps include upper abdominal (belly) pain, dizziness and joint pain.

In children aged 6 to 12 years with allergic asthma, the most common side effects include headache and fever (which may affect more than 1 in 10 people), and upper abdominal pain (which may affect up to 1 in 10 people).

In people with chronic spontaneous urticaria, the most common side effects include headache, injection site reactions, joint pain, sinusitis and upper respiratory tract infections (nose and throat infections).

Why is Omlyclo authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Omlyclo has a highly similar structure, purity and biological activity to Xolair and is distributed in the body in the same way. In addition, a study involving patients with chronic spontaneous urticaria has shown that Omlyclo and Xolair are equivalent in terms of safety and effectiveness in this condition.

All these data were considered sufficient to conclude that Omlyclo will have the same effects as Xolair in its authorised uses. Therefore, the Agency's view was that, as for Xolair, the benefits of Omlyclo outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Omlyclo

Omlyclo received a marketing authorisation valid throughout the EU on 16 May 2024.

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

This overview was last updated in 04-2024.