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Benlysta (*belimumab*)

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

What is Benlysta and what is it used for?

Benlysta is a medicine used as an add-on treatment in people aged 5 years and older with systemic lupus erythematosus (SLE), a disease in which the immune system (the body's natural defences) attacks normal cells and tissues, causing inflammation and organ damage. Benlysta is given to people whose disease is still highly active despite standard treatment.

Benlysta is also used in adults to treat active lupus nephritis, a manifestation of SLE causing kidney damage. In this case, it is given in combination with different immunosuppressants (medicines that reduce the activity of the immune system).

Benlysta contains the active substance belimumab.

How is Benlysta used?

Benlysta can only be obtained with a prescription, and treatment should only be started and supervised by a doctor who has experience in the diagnosis and treatment of SLE.

Benlysta is available as three different formulations including an infusion (drip) given into a vein and a pre-filled pen and pre-filled syringe. The pre-filled pen and pre-filled syringe are both injected under the skin.

Both the infusion given into a vein and the pre-filled pen can be used in adults and children. However, the pre-filled syringe is for use in adults only.

When Benlysta is given as an infusion into a vein for the treatment of SLE in adults and children or for the treatment of active lupus nephritis in adults, the recommended dose depends on the patient's body weight. The first three doses are given at two-week intervals. After this, Benlysta is given once every four weeks.

In adults with SLE, Benlysta can also be given by either the pre-filled pen or the pre-filled syringe once a week. In children with SLE, the recommended dose of the pre-filled pen depends on the patient's body weight.

In adults with active lupus nephritis, the medicine is given as two injections under the skin (either by the pre-filled pen or pre-filled syringe) once a week for the first 4 weeks. They can then move to one injection given once weekly.

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Patients may inject Benlysta themselves once they have been trained to do so and if the doctor considers this appropriate. However, for children under 10 years of age, injections must be given by either a healthcare professional or a trained carer.

If the medicine is given as an infusion, patients may develop reactions linked to the infusion (such as rash, itchiness and difficulty breathing) or hypersensitivity (allergic) reactions which may be severe and life-threatening and can develop several hours after Benlysta is given. Patients should therefore be observed for several hours after at least the first two infusions. All infusions with Benlysta, and the first injection under the skin, should be given in a place where these reactions can be managed immediately if they occur. If the patient develops a reaction linked to the infusion or injection the doctor may interrupt or stop treatment.

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

How does Benlysta work?

SLE can affect almost any organ in the body and is thought to involve a type of white blood cell called B lymphocytes. Usually, B lymphocytes produce antibodies which help to fight infections. In SLE, some of these antibodies attack the body's own cells and organs instead (autoantibodies). In lupus nephritis, the autoantibodies attack the kidneys, stopping them from working properly. The active substance in Benlysta, belimumab, is a monoclonal antibody, a protein that has been designed to attach to and block a protein called BLyS which helps B lymphocytes to live longer. By blocking the action of BLyS, belimumab reduces the life span of B lymphocytes, thereby reducing the inflammation and organ damage that occur in SLE and lupus nephritis.

What benefits of Benlysta have been shown in studies?

Benlysta given by infusion was shown to be more effective than placebo (a dummy treatment) in reducing disease activity when used as an add-on treatment for SLE in two main studies involving 1,693 adult patients with active SLE. In the first study, disease activity decreased in 43% of patients treated with Benlysta, compared with 34% of patients who were given placebo. In the second study, disease activity decreased in 58% of patients treated with Benlysta, compared with 44% of patients who were given placebo.

Results from two studies involving 118 children aged 5 to 17 years with active SLE showed that Benlysta was distributed in the body in a similar way as in adults and could be expected to have similar benefits.

Another study involved 836 adult patients with active SLE, who received add-on Benlysta as an injection under the skin once a week for a year. The study showed that disease activity decreased in 61% of patients treated with Benlysta, compared with 48% of patients given placebo.

A study in 448 patients aged 18 or above with active lupus nephritis showed that, after 2 years, 43% of patients given Benlysta had acceptable kidney function and levels of protein in the urine (a sign of kidney damage), compared with 32% in the placebo group. All patients received standard immunosuppressive therapy for active lupus nephritis in addition to Benlysta or to placebo.

What are the risks associated with Benlysta?

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

The most common side effects with Benlysta when it is used as an add-on treatment for SLE (which may affect up to 1 in 20 people) includes nasopharyngitis (inflammation of the nose and throat).

The most common side effects with Benlysta when it is used with immunosuppressants to treat lupus nephritis (which may affect up to 1 in 20 people) include upper respiratory tract (nose and throat) infection, infection of the urinary tract (structures that carry urine) and herpes zoster (shingles).

Some side effects can be serious. Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals) and toxic epidermal necrolysis (life-threatening reaction with flu-like effects and blistering in the skin, mouth, eyes and genitals) have been reported with Benlysta.

Why is Benlysta authorised in the EU?

The Agency considered that Benlysta, used as an add-on treatment, reduced disease activity in SLE. In SLE patients with active lupus nephritis, for whom there is a high unmet medical need, Benlysta used with immunosuppressants reduced damage to the kidneys. The medicine may cause infusion and hypersensitivity reactions as well as infections but is generally well tolerated. The Agency also noted the lack of effective alternative treatments for patients who have already tried standard treatments. Benlysta was shown to be absorbed, modified and removed from the body in a similar way in children as it is in adults. The European Medicines Agency therefore decided that Benlysta's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets Benlysta will provide further information on the safety of the medicine from a register of patients being followed up long-term.

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

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

Other information about Benlysta

Benlysta received a marketing authorisation valid throughout the European Union on 13 July 2011.

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

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