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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 patients 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 patients 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 given as an infusion (drip) into a vein; it is also available as a pre-filled pen and pre-filled syringe for injection under the skin.

When Benlysta is given as an infusion into a vein, the recommended dose is 10 mg per kilogram body weight given over one hour. 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 as a 200-mg injection under the skin, once a week. In adults with active lupus nephritis, patients receiving Benlysta for the first time should be given a 400-mg dose injection under the skin (as two 200 mg injections) once a week for the first 4 weeks, then move to a 200-mg dose once weekly. Patients may inject Benlysta themselves once they have been properly trained, if the doctor considers this appropriate.

The doctor may interrupt or stop treatment if the patient develops 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

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Benlysta, and the first injection under the skin, should be given in a place where these reactions can be managed immediately if they occur.

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, in particular, 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.

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 a main study involving 93 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?

The most common adverse effects with Benlysta added to treatment for SLE (which may affect more than 1 in 10 patients) are viral upper respiratory tract infections, bronchitis (bacterial lung infection) and diarrhoea. The most common adverse effects when Benlysta was used with immunosuppressants to treat lupus nephritis are upper respiratory tract infection, infection of the urinary tract (structures that carry urine) and *Herpes zoster* (shingles). For the full list of side effects and restrictions of Benlysta, see the package leaflet.

Why is Benlysta authorised in the EU?

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

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 study and 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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