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EPAR summary for the public

Benlysta

belimumab

This is a summary of the European public assessment report (EPAR) for Benlysta. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Benlysta.

For practical information about using Benlysta, patients should read the package leaflet or contact their doctor or pharmacist.

What is Benlysta and what is it used for?

Benlysta is a medicine used as an add-on treatment for adults 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 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 a powder (120 mg and 400 mg) that is made up into a solution for infusion (drip) into a vein; it is also available as a pre-filled pen and pre-filled syringe (200 mg) 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. Benlysta can also be given as a 200-mg injection under the skin, once a week. 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

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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.

For further information, see the package leaflet.

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).

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 benefit 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.

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.

What are the risks associated with Benlysta?

The most common side effects with Benlysta (which may affect more than 1 patient in 10) are bacterial infections, such as bronchitis (infection in the lungs) and infection of the urinary tract (structures that produce or carry urine), diarrhoea and nausea (feeling sick). For the full list of all side effects and restrictions with Benlysta, see the package leaflet.

Why is Benlysta approved?

The European Medicines Agency considered that Benlysta, used as an add-on treatment, reduced disease activity in SLE. 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. The Agency decided that Benlysta's benefits are greater than its risks and recommended that it be given marketing authorisation.

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.

Other information about Benlysta

The European Commission granted a marketing authorisation valid throughout the European Union for Benlysta on 13 July 2011.

The full EPAR for Benlysta can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Benlysta, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2017.