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EPAR summary for the public

Lemtrada

alemtuzumab

This is a summary of the European public assessment report (EPAR) for Lemtrada. 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 Lemtrada.

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

What is Lemtrada and what is it used for?

Lemtrada is a medicine that is used to treat adults with relapsing-remitting multiple sclerosis, a disease of the nerves in which inflammation destroys the protective sheath surrounding the nerve cells. 'Relapsing-remitting' means that the patient has flare-ups of symptoms (relapses) followed by periods of recovery (remissions). Lemtrada is used for patients with active disease, based on the patient's symptoms or scan results.

Lemtrada contains the active substance alemtuzumab.

How is Lemtrada used?

Lemtrada can only be obtained with a prescription. Treatment should be started and supervised by a doctor experienced in treating multiple sclerosis. Suitable equipment and staff should be available for managing the most common side effects and hypersensitivity (allergic) reactions. Patients should receive certain medicines before or during treatment to reduce the side effects.

Lemtrada is available as a liquid to be made up into a solution for infusion (drip) into a vein. An infusion lasts around 4 hours. Lemtrada is initially given in two courses of treatment: a first course of 12 mg daily for 5 days, followed 12 months later by a second course of 12 mg daily for 3 days. Up to two additional courses, each of 12 mg daily for 3 days, can be given at 12-month intervals.

For further information, see the package leaflet.

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How does Lemtrada work?

In multiple sclerosis, the immune system (the body's defences) incorrectly attacks the protective sheath around the nerves in the brain and spinal cord. The active substance in Lemtrada, alemtuzumab, is a monoclonal antibody, a type of protein that has been designed to recognise and attach to a protein called CD52. CD52 is found on lymphocytes, white blood cells that are part of the immune system. When alemtuzumab attaches to the lymphocytes it causes them to die, and they are replaced by new lymphocytes. The way alemtuzumab acts in multiple sclerosis is not fully understood, but it is believed to reduce the immune system's damaging activity by causing the existing lymphocytes to die and to be replaced by new ones.

What benefits of Lemtrada have been shown in studies?

Lemtrada has been studied in two main studies involving 1,421 patients with relapsing-remitting multiple sclerosis. In both studies, Lemtrada was compared with another medicine for multiple sclerosis, interferon beta-1a. The first study involved previously untreated patients, while the second study involved patients whose disease had relapsed despite treatment. In both studies, the main measure of effectiveness was based on the number of relapses the patients had each year and the progression of disability after 2 years of treatment.

In the first study, the average number of relapses per year in patients given Lemtrada was less than half the number in patients given interferon beta-1a (0.18 versus 0.39), but there was no meaningful effect in terms of progression of disability. In the second study, the average number of relapses per year in patients given Lemtrada was around half the number in patients given interferon beta-1a (0.26 versus 0.52), and around 13% of patients given Lemtrada had a sustained progression of disability compared with around 21% of patients given interferon beta-1a.

Patients involved in the two main studies were followed-up for at least four years in an extension study, during which they were given up to two additional doses of Lemtrada, at one-year intervals, if their disease progressed. Over half of patients included in the extension study did not have disease progression and did not need additional Lemtrada infusions. For those patients who needed one or two additional infusions with Lemtrada, the number of relapses was lower, and disability progression was slower, compared with the previous year.

What are the risks associated with Lemtrada?

The most important side effects with Lemtrada are autoimmune conditions (where the body's defence system attacks normal tissue), including thyroid gland disorders, immune thrombocytopenic purpura (ITP, a bleeding disorder caused by low blood platelet counts) and kidney damage, as well as red and white blood cell disorders, reactions to the infusion and infections. The most common side effects with Lemtrada (which may affect more than 2 in 10 people) are rash, headache, fever and respiratory tract infections (throat and chest infections). For the full list of side effects reported with Lemtrada, see the package leaflet.

Lemtrada must not be used in patients with HIV and in patients with severe infections. For the full list of restrictions, see the package leaflet.

Why is Lemtrada approved?

The European Medicines Agency decided that Lemtrada's benefits are greater than its risks and recommended that it be approved for use in the EU. The Agency considered that the benefit for patients with active disease had been shown in studies. With regards to safety, the Agency considered that educational materials must be provided to prescribers and patients to reduce the medicine's risks.

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

The company that markets Lemtrada will ensure that doctors expected to prescribe the medicine receive educational materials containing important safety information, including details of the risk of autoimmune conditions, and a checklist covering the necessary screening, pre-treatment and long-term monitoring of patients. This will also contain a patient alert card and a guide for patients explaining participation in the risk management programme.

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

Other information about Lemtrada

The European Commission granted a marketing authorisation valid throughout the European Union for Lemtrada on 12 September 2013.

The full EPAR for Lemtrada 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 Lemtrada, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2018.