



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 contains the active substance alemtuzumab. It 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 when the disease is known to be active, based on the patient's symptoms or scan results.

How is Lemtrada used?

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

Lemtrada is available as a liquid to be made up into a solution for infusion (drip) into a vein. An infusion provides 12 mg and lasts around 4 hours. Lemtrada is given in two courses of treatment: a first course of 12 mg per day for 5 consecutive days, followed 12 months later by a second course of 12 mg per day for 3 consecutive days. For further information, see the package leaflet.



How does Lemtrada work?

In multiple sclerosis, the body's immune system malfunctions and attacks parts of the central nervous system (the brain and spinal cord), destroying the protective sheath around the nerves. The active substance in Lemtrada, alemtuzumab, is a monoclonal antibody, a type of protein that has been designed to recognise and attach to glycoprotein CD52, an antigen found on the surface of 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 exact 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 lymphocytes.

The monoclonal antibody in Lemtrada is produced using a method known as 'recombinant DNA technology': it is made by cells into which a gene (DNA) has been introduced that makes the cells able to produce the antibody.

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, Rebif (interferon beta-1a). The first study involved previously untreated patients, while the second study involved patients whose disease had relapsed despite previous treatment. In both studies, the main measure of effectiveness was based on the number of relapses the patients experienced 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 observed 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 experienced a sustained progression of disability compared with around 21% of patients given interferon beta-1a.

What are the risks associated with Lemtrada?

The most important side effects with Lemtrada are autoimmune conditions (where the body's own 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, pyrexia (fever) and respiratory tract infections. For the full list of all side effects reported with Lemtrada, see the package leaflet.

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

Why is Lemtrada approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Lemtrada's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered that the benefit for patients with active disease had been demonstrated in studies. With regards to safety, the CHMP 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?

A risk management plan has been developed to ensure that Lemtrada is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Lemtrada, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, 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.

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 09-2013.