Treatments for MS:

Lemtrada® (alemtuzumab)

There is a range of disease modifying therapies approved for people with relapsing MS in Australia. These therapies, also called immunotherapies, work to reduce disease activity in the central nervous system and reduce the frequency and severity of relapses in people with MS.

What is Lemtrada® and how does it work?

Lemtrada® is a monoclonal antibody. Lemtrada® is the brand name for alemtuzumab in Australia.

In MS, certain types of white blood cells called lymphocytes play a role in destroying myelin, the protective sheath that surrounds nerve fibres and helps with the efficient flow of nerve signals or messages to and from the brain and various parts of the body.

Lemtrada® works on the immune system. It is thought to work in MS through depletion and repopulation of lymphocytes so that it may reduce the impact of the disease on your nervous system.

Lemtrada® is used to treat relapsing remitting multiple sclerosis (RRMS) in adults with active disease. It is not recommended for patients with inactive disease or those who are stable on their current therapy.

In clinical trials[1], Lemtrada® has been shown to:

- reduce the frequency of relapses when compared with interferon beta treatment.[2,3]
- delay the progression of disability in some people when compared to interferon beta treatment.[3]

How is Lemtrada® administered?

Lemtrada® is given by intravenous infusion over two treatment courses. For the first treatment course you will receive one infusion per day on 5 consecutive days. One year later you will receive one infusion per day on 3 consecutive days.

Lemtrada® infusions are usually administered in a hospital under the supervision of a neurologist. Each infusion takes approximately 4 hours.

What are the potential side effects of Lemtrada® treatment?

Lemtrada® helps most people with MS, but it may have side effects in some people. Potential side effects of Lemtrada® treatment include infusion-associated reactions (IAR), infections and development of autoimmune conditions.

<u>Infusion-associated reactions</u>

IAR, such as headache, rash, fever and nausea, are common and occur at the time of the infusion or within 24 hours after the infusion. Most infusion reactions are mild. To minimise the risk of IAR, medications are given prior to infusion of Lemtrada® and you will be monitored during and after the infusion so that any reactions can be managed promptly.

Infections

Lemtrada® increases your risk of getting infections. Infections are usually mild or moderate in severity but in some cases can be serious. You may have an increased chance of getting an infection caused by the bacteria Listeria. It is recommended to avoid food that might be a source of Listeria if you are being treated with Lemtrada®.

Autoimmune conditions

Lemtrada® can increase your risk of developing certain auto-immune conditions. These include thyroid disorders (overactive or underactive thyroid), immune thrombocytopenic purpura (a bleeding disorder, also called ITP) and, rarely, kidney disorders.

These autoimmune conditions can develop many years after Lemtrada® treatment and can be very serious if left undiagnosed and untreated. You will need to undergo regular (monthly) blood testing from before treatment starts and for four years after your last infusion to ensure that these conditions can be detected early and treated promptly.

Women of childbearing potential should use a reliable and effective contraceptive when receiving a course of treatment with Lemtrada® and for four months following that course of treatment. Breastfeeding should be discontinued during each course of treatment and for four months following that course of treatment.

Your doctor or pharmacist can provide comprehensive information on the use of Lemtrada®, including precautions and side effects.

How much does Lemtrada® cost?

Lemtrada® has been approved by the Therapeutic Goods Administration (TGA) and is available through the Pharmaceutical Benefits Scheme (PBS). Please discuss with your neurologist whether Lemtrada® is the right treatment for you.

Lemtrada® is listed on the PBS under the Highly Specialised Drugs Program, which means there are restrictions on where it can be prescribed and dispensed. Generally the clinic where you have Lemtrada® infused will take care of your prescription and order the medication for you.

If you are eligible for medications through the PBS, you will need to pay a contribution fee each time your prescription is dispensed. The Federal Government pays for the remaining cost. The amount of the contribution fee depends upon whether or not you have a pension or concession card. The amount of this fee is set each year by the Federal Government.

Further information about the PBS, your entitlements and details regarding the PBS safety net (which protects patients and their families requiring a large number of PBS items) is available through the Medicare Australia website at: www.medicare.gov.au

If you are not eligible for Lemtrada® through the PBS, for example if you are a visitor from overseas, your neurologist may write a private prescription. In this instance you will have to pay the full cost to the pharmacy that dispenses your medication. You will need to request a quote from your pharmacist for the price of any medication which is not subsidised by the PBS.

General information

In Australia Lemtrada® is supplied by:
Sanofi Genzyme, Building D,12-24 Talavera Rd
Macquarie Park,NSW - 2113

For more information on MS and other MS treatments

- Speak to your neurologist about what treatment best suits your individual circumstances.
- MS Nurses can also provide information, training and ongoing support in managing your immunotherapy.
- For information about MS, MS treatment and to find contact details for your state MS organization visit **www.msaustralia.org.au**
- MS Research Australia provides information on the latest research and clinical trials at www.msra.org.au

References

1. Lemtrada® Approved Product Information, December 2015 https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2013-PI-02549-1
2. Cohen JA, Coles AJ, Arnold DL et al., Alemtuzumab versus interferon beta 1a as first-line treatment for patients with relapsing-remitting multiple sclerosis: a randomised controlled phase 3 trial. Lancet. 2012;380(9856):1819-28.
3. Coles AJ, Twyman CL, Arnold DL et al., Alemtuzumab for patients with relapsing multiple sclerosis after disease-modifying therapy: a randomised controlled phase 3 trial. Lancet. 2012;380(9856):1829-3

Note:

MS Australia does not recommend any specific disease-modifying treatment for people living with MS. Decisions about any treatments, taking into consideration the potential benefits and side effects for each individual's circumstances, should be made in careful consultation with the person's neurologist.

The information supplied in this document is collated from material provided by the relevant pharmaceutical company, MIMS (http://www.mims.com.au) and MS Research Australia.