Treatments for MS:

Kesimpta® (ofatumumab)

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

What is Kesimpta and how does it work?

Kesimpta® (ofatumumab) is a self-administered therapy used for the treatment of adults with the relapsing forms of MS to delay the progression of physical disability and reduce the frequency of relapse**.**

Kesimpta contains the active ingredient ofatumumab. Kesimpta is a monoclonal antibody, a type of drug developed to attack specific targets, in this case a target in the immune system. It binds to a marker (CD20) on the surface of B lymphocytes, a type of white blood cell which is thought to influence the abnormal immune response that causes the attack on the myelin coating of nerves. Kesimpta reduces the number of B lymphocytes in the body.

How is Kesimpta administered?

Kesimpta is intended for self-administration by subcutaneous (under the skin) injection.

The usual sites for subcutaneous injections are the abdomen, the thigh and the upper outer arm.

The first injection of Kesimpta should be performed under the guidance of a healthcare professional. Comprehensive instructions for administration are provided in the instructions for use and handling.

The recommended dose is 20 mg Kesimpta administered by subcutaneous injection with: initial dosing at weeks 0, 1 and 2, followed by subsequent monthly dosing, starting at week 4.

Missed Doses: If an injection of Kesimpta is missed, it should be administered as soon as possible without waiting until the next scheduled dose. Subsequent doses should be administered at the recommended intervals.

What are the possible side effects of Kesimpta?

Kesimpta is indicated for the treatment of adults with relapsing forms of multiple sclerosis (RMS) to delay the progression of physical disability and reduce the frequency of relapse, but it may have unwanted side effects in some people. All medicines can have side effects. Tell your doctor if you notice anything that is making you feel unwell.

Side effects of Kesimpta may include injection-related reactions. Contact your doctor immediately if you notice any of the following symptoms while self-administering an injection. Injection site reaction (local) symptoms may include erythema (redness of the skin), swelling, itching and pain. Injection-related reactions observed in clinical studies occurred predominantly with the first injection. Symptoms observed include fever, headache, myalgia (muscle aches and pains), chills and fatigue and were predominantly non-serious and mild to moderate in severity.

As well as injection-related reactions and injection site reaction, the most common side effects of Kesimpta include nasopharyngitis (symptoms of the common cold) and urinary tract infection.

Kesimpta should not be given to patients with severe immunosuppression (e.g. significant neutropenia or lymphopenia).

Patients with active hepatitis B disease should not be treated with Kesimpta. Hepatitis B virus screening should be performed in all patients before initiation of treatment with Kesimpta.

Kesimpta has not been tested in women who are pregnant or breastfeeding; therefore the side effects are unknown. Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Kesimpta has not been studied in patients below 18 years.

Tell your doctor if you are taking any other medicines, including any that you get without prescription from a pharmacy, supermarket or health food shop.

How much does Kesimpta cost?

Kesimpta was registered in the Therapeutic Goods Administration (TGA) on 5 March 2021 for the treatment of adults with the relapsing forms of MS in Australia to delay the progression of physical disability and reduce the frequency of relapse.

Kesimpta was recommended for listing on the Pharmaceutical Benefits Scheme (PBS) by the Pharmaceutical Benefits Advisory Committee (PBAC) on 23 April 2021. Its listing on the PBS is subject to final approval by the Federal Health Minister.

Please consult your neurologist if you are interested in this medication to see if Kesimpta is the right treatment for you.

General information

Kesimpta comes in a box containing a pre-filled pen which contains 20 mg ofatumumab solution for injection (0.4 mL of 50 mg/mL solution).

Kesimpta needs to be stored in the refrigerator between 2°C to 8°C. Do not freeze.

In Australia, Kesimpta is supplied by:

Novartis Pharmaceuticals Australia Pty Ltd

54 Waterloo Road

North Ryde NSW 2113 Australia

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 organisation, please visit **www.msaustralia.org.au**
- For information on the latest research and clinical trials please visit: **www.msra.org.au**

References:

1. MS Trust UK – https://mstrust.org.uk/a-z/ofatumumab
2. MS Research Australia news item regarding ofatumumab, including links to, and details regarding, the clinical trials
3. Consumer Medicine Information (CMI) from the TGA website , please visit: https://www.tga.gov.au/ and search for Kesimpta.

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, and the research division of MS Australia.