

Treatment

Kesimpta[®] (ofatumumab)

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

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 multiple sclerosis 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?

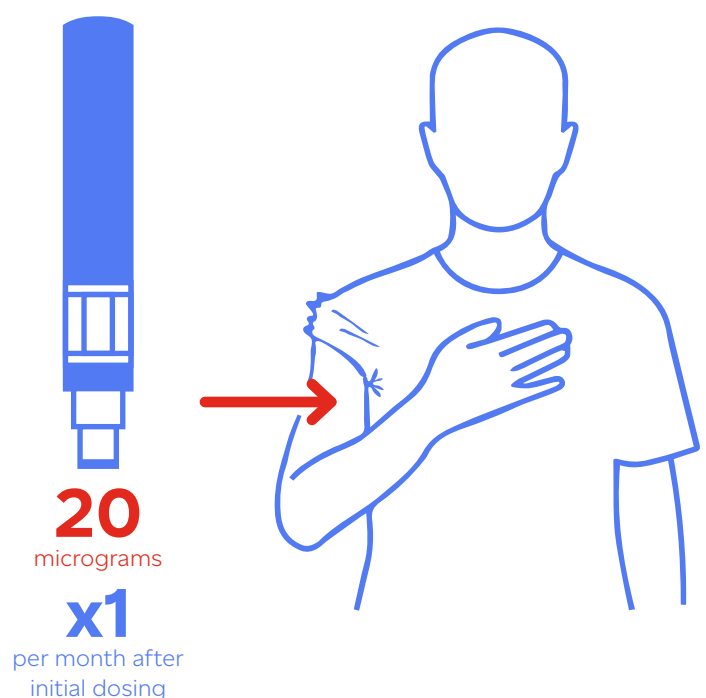
Kesimpta® is intended for self-administration by subcutaneous (under the skin) injection.

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 micrograms 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 breastfeeding.

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 by the Therapeutic Goods Administration (TGA) on 5 March 2021 for the treatment of adults with relapsing forms of MS in Australia. Kesimpta® has been available through the Pharmaceutical Benefits Scheme (PBS) from 1 October 2021. Your neurologist will need to obtain an authority to prescribe the medication for you.

For details of the criteria required to receive a prescription for Kesimpta® treatment through the PBS, please visit the official PBS website at: <https://www.pbs.gov.au/pbs/home>

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 Kesimpta® 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

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



2°C – 8°C

Storage
temperature

Do not freeze

For more information on multiple sclerosis and other multiple sclerosis 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.
- We can provide emotional and practical support for every stage of your journey. For more information visit www.msplus.org.au
- For more information about multiple sclerosis treatments, research, clinical trials and for your state MS organisation visit www.msaustralia.org.au

References

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

Note

MS Plus does not recommend any specific disease-modifying treatment for people living with multiple sclerosis. 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 MS Australia.