What is Kesimpta?

Kesimpta contains the active substance ofatumumab. Ofatumumab belongs to a group of medicines called monoclonal antibodies. Kesimpta is a type of B cell therapy which can be taken by a subcutaneous injection (injection under the skin), rather than by infusion. It is known as a disease modifying therapy (DMT) and targets the immune system to reduce relapses.

How does Kesimpta work?

Kesimpta works by attaching to a target called CD20 on the surface of B cells. B cells are a type of white blood cell which are part of the immune system (the body's defences). In multiple sclerosis, the immune system attacks the protective layer around nerve cells. B cells are involved in this process. Kesimpta targets and removes the B cells and thereby reduces the chance of a relapse, relieves symptoms and slows down the progression of the disease.

Who should take Kesimpta?

Kesimpta is used to treat adults with relapsing forms of multiple sclerosis (RMS).

How is Kesimpta administered?

Kesimpta is given by subcutaneous injection (injection under your skin) using the Sensoready® autoinjector pen. The first injection should take place under the guidance of a healthcare professional. You will have the option for a Novartis nurse to come to your home to teach you how to use the Kesimpta pre-filled pen. Kesimpta pre-filled pens are for single use only. You can use Kesimpta at any time of day (morning, afternoon, or evening).

The initial dosing is 20 mg Kesimpta administered on the first day of treatment (Week 0) and after 1 and 2 weeks (Week 1 and Week 2). After these first 3 injections, there is no injection in the following week (Week 3). Starting at Week 4 and then every month, the recommended dose is 20 mg Kesimpta.

What are the side effects from taking Kesimpta?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects of Kesimpta are listed below. If any of these side effects becomes severe, tell your doctor, pharmacist or nurse.

Very common (may affect more than 1 in 10 people)
- upper respiratory tract infections, with symptoms such as sore throat and runny nose

- injection-related reactions, such as fever, headache, muscle pain, chills and tiredness – these usually occur in the 24 hours after an injection of Kesimpta, in particular after the first injection
- urinary tract infections
- injection-site reactions, such as redness, pain, itching and swelling at the injection site

Common (may affect up to 1 in 10 people)
- decrease in the blood level of a protein called immunoglobulin M, which helps protect against infection
- oral herpes

What are the findings from Kesimpta clinical trials?

Two main studies have provided the evidence to support Kesimptaas a treatment for RMS. ASCLEPIOS1 and ASCLEPIOS2 tested how effective Kesimpta was at treating RMS and assessed its safety profile, compared to teriflunomide in people with RMS.

Kesimpta reduced the number of relapses compared with teriflunomide and reduced the chance of getting new active lesions (measured by magnetic resonance imaging) during the study compared with teriflunomide. Overall, treatment with ofatumumab also slowed down disability progression more than treatment with teriflunomide in participants with RMS. Kesimpta was found to have a safety profile which was similar to teriflunomide.

Further information on these clinical studies can be found at:
• **www.clinicaltrials.gov** – once you are on this website, type **NCT02792218** for ASCLEPIOS 1 or **NCT02792231** forASCLEPIOS 2 into the search box and click "**Search**".
• **www.clinicaltrialsregister.eu** – once you are on this website, type **2015-005418-31** for ASCLEPIOS 1 or **2015-005419-33** forASCLEPIOS 2 into the search box and click "**Search**".

When was Kesimpta made available?

From 1st February 2022, Mayzent is available under the High-Tech Drug Scheme in Ireland.

As of September 25, 2021, a total of approximately 2,560 patients with relapsing multiple sclerosis (RMS) received ofatumumab in clinical trials including the ongoing open-label extension.