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Kesimpta (*ofatumumab*)

An overview of Kesimpta and why it is authorised in the EU

What is Kesimpta and what is it used for?

Kesimpta is a medicine for treating adults with relapsing forms of multiple sclerosis (MS), where the patient has flare-ups (relapses) followed by periods with milder or no symptoms. It is used in patients with active disease, which means that they have relapses and/or signs of active inflammation on scans.

Kesimpta contains the active substance ofatumumab.

How is Kesimpta used?

Kesimpta can only be obtained with a prescription and treatment should be started by a doctor experienced in the management of conditions of the nervous system.

Kesimpta is available as a solution for injection in prefilled syringes or prefilled pens. Treatment starts with one injection under the skin every week for 3 weeks, followed by a week with no injection. The next injection is given a week later and then an injection is given every month. Patients can inject themselves with Kesimpta once they have been trained.

For more information about using Kesimpta, see the package leaflet or contact your doctor or pharmacist.

How does Kesimpta work?

The active substance in Kesimpta, ofatumumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a specific target called CD20 on the surface of B cells (a type of white blood cell).

B cells play a key role in multiple sclerosis by attacking the protective covering (sheaths) around the nerves in the brain and spinal cord, causing inflammation and damage. By targeting B cells, Kesimpta helps to reduce their activity and thereby relieves symptoms or slows down the worsening of the disease.

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What benefits of Kesimpta have been shown in studies?

Studies have shown that Kesimpta is effective at reducing the number of relapses and can also delay the worsening of symptoms.

In two main studies of 1,882 patients with relapsing forms of multiple sclerosis, the average number of relapses in a year in patients treated with Kesimpta was less than half that in patients treated with another multiple sclerosis medicine, teriflunomide (0.11 versus 0.24 relapses per year). The studies also showed that fewer patients taking Kesimpta (8%) had worsening symptoms lasting 6 months or more compared with those taking teriflunomide (12%).

What are the risks associated with Kesimpta?

The most common side effects with Kesimpta (which may affect more than 1 in 10 people) are upper respiratory tract infections (nose and throat infections), urinary tract infections (infections of the structures that carry urine), reactions at the site of injection (redness, pain, itching, and swelling) and injection-related reactions (fever, headache, muscle pain, chills and tiredness).

For the full list of side effects of Kesimpta, see the package leaflet.

Kesimpta must not be used in patients with severe active infections, severely weakened immune systems or cancer.

For the full list of restrictions, see the package leaflet.

Why is Kesimpta authorised in the EU?

Studies showed that Kesimpta was more effective than teriflunomide at reducing the number of relapses in patients with relapsing forms of multiple sclerosis. The medicine was also more effective at delaying the worsening of symptoms. Side effects are in line with those of other similar medicines and are considered manageable. The European Medicines Agency decided that Kesimpta's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Kesimpta?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Kesimpta have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of the medicine are continuously monitored. Side effects reported with the medicine are carefully evaluated and any necessary action taken to protect patients.

Other information about Kesimpta

Kesimpta received a marketing authorisation valid throughout the EU on 26 March 2021.

Further information on Kesimpta can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/kesimpta.

This overview was last updated in 03-2021.