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EPAR summary for the public

Ocrevus

ocrelizumab

This is a summary of the European public assessment report (EPAR) for Ocrevus. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Ocrevus.

For practical information about using Ocrevus, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ocrevus and what is it used for?

Ocrevus is a medicine for treating multiple sclerosis – an inflammatory disease of the nervous system that causes symptoms such as weakness, difficulty walking and problems with vision.

Ocrevus is used in two types of patients:

- adults with relapsing forms of multiple sclerosis (RMS), where the patient has flare-ups (relapses) followed by periods with milder or no symptoms;
- adults with primary progressive multiple sclerosis (PPMS), where symptoms get steadily worse over time.

Ocrevus contains the active substance ocrelizumab.

How is Ocrevus used?

Ocrevus is given as an infusion (drip) into a vein. The first two infusions are given two weeks apart and subsequent infusions are given every six months.

Before each infusion, the patient is given other medicines (a corticosteroid and an antihistamine) to help to prevent potentially dangerous reactions. If reactions occur during an infusion it may be stopped



or given more slowly. The patient should be monitored during the infusion and for at least an hour afterwards, and facilities to manage severe reactions should be readily available.

Ocrevus can only be obtained with a prescription and treatment must only be started and supervised by a doctor experienced in treating diseases of the nerves. For further information, see the package leaflet.

How does Ocrevus work?

The active substance in Ocrevus, ocrelizumab, is a monoclonal antibody designed to recognise and attach to a target called CD20 on the surface of certain types of white blood cells (so called B cells).

These white blood cells play a role in multiple sclerosis by attacking the sheaths around the nerves in the brain and spinal cord, causing inflammation and damage. By targeting the B cells, Ocrevus helps to reduce their activity and thereby relieves symptoms or slows down the worsening of the disease.

What benefits of Ocrevus have been shown in studies?

Studies have shown that Ocrevus is effective at reducing the number of relapses and it can also reduce the worsening of symptoms in some patients.

In two studies of 1,656 patients with relapsing forms of multiple sclerosis (RMS), the average number of relapses in patients treated with Ocrevus was about half that in patients treated with another medicine interferon beta-1a (0.16 versus 0.29 relapses per year).

A third study, in 732 patients with primary progressive multiple sclerosis (PPMS), showed that fewer patients taking Ocrevus had worsening symptoms lasting 12 weeks or more (30%) compared with those taking a placebo (34%).

What are the risks associated with Ocrevus?

The most important and most frequently reported side effects with Ocrevus are infusion reactions (such as itching, rash, and difficulty breathing) and infections. These occur in more than 1 in 10 people. For the full list of side effects reported with Ocrevus, see the package leaflet.

Ocrevus must not be used in patients with active infections or severely weakened immune systems or in patients with cancer. For the full list of restrictions, see the package leaflet.

Why is Ocrevus approved?

Studies showed that Ocrevus was more effective than interferon beta-1a at reducing the number of relapses in patients with relapsing forms of multiple sclerosis. Ocrevus treatment also provided some benefit in patients with primary progressive multiple sclerosis, a condition for which treatments are urgently needed.

The European Medicines Agency concluded that the benefits seen with Ocrevus outweighed its risks and recommended that it be authorised in the EU.

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

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

Other information about Ocrevus

The European Commission granted a marketing authorisation valid throughout the European Union for Ocrevus on 8 January 2018.

The full EPAR for Ocrevus can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Ocrevus, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2018.