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Briumvi (*ublituximab*)

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

What is Briumvi and what is it used for?

Briumvi is a medicine for treating adults with relapsing forms of multiple sclerosis (a disease of the brain and spinal cord in which inflammation destroys the protective covering around nerves and damages the nerves), 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.

Briumvi contains the active substance ublituximab.

How is Briumvi used?

The medicine can only be obtained with a prescription and treatment should be started by a doctor experienced in the diagnosis and treatment of conditions of the nervous system and who has access to appropriate medical support to manage severe reactions such as serious infusion-related reactions.

Briumvi is available as a solution for infusion. Treatment starts with one infusion (drip) into a vein followed by another infusion 2 weeks later. After the first two doses, infusions are given every 24 weeks.

To reduce the risk of infusion-related reactions, patients will receive other medicines before treatment.

For more information about using Briumvi, see the package leaflet or contact your healthcare provider.

How does Briumvi work?

The active substance in Briumvi, ublituximab, 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 and the nerves themselves, causing inflammation and damage. By targeting B cells, ublituximab helps to reduce their activity and helps to prevent flare-ups.

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What benefits of Briumvi have been shown in studies?

Studies have shown that Briumvi is effective at reducing the number of relapses.

In two main studies of 1,089 patients with relapsing forms of multiple sclerosis, the average number of yearly relapses in patients treated with Briumvi was less than half that in patients treated with another multiple sclerosis medicine, teriflunomide (0.09 versus 0.23 relapses per year). The studies also showed that patients treated with Briumvi had fewer lesions in scans of the brain than patients taking teriflunomide (0.013 versus 0.38 lesions per scan) indicating less active multiple sclerosis.

What are the risks associated with Briumvi?

For the full list of side effects and restrictions with Briumvi, see the package leaflet.

The most common side effects with Briumvi (which may affect more than 1 in 10 people) include infusion-related reactions and infections.

Why is Briumvi authorised in the EU?

Studies showed that Briumvi is effective at reducing the number of relapses in patients with relapsing forms of multiple sclerosis. While Briumvi did not show a significant impact in terms of preventing disability due to MS from getting worse, this could be attributed to the low number of patients whose disease progressed in the study. Side effects are in line with those of other similar medicines and are considered manageable. The European Medicines Agency decided that Briumvi'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 Briumvi?

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

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

Other information about Briumvi

Briumvi received a marketing authorisation valid throughout the EU on 31 May 2023.

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

This overview was last updated in June 2023.