What is ublituximab (Briumvi)?

Briumvi is a disease modifying therapy which is available for relapsing forms of MS with active disease. Briumvi's active substance is called Ublituximab, which belongs to a group of medicines called monoclonal antibodies.

How does ublituximab (Briumvi) work?

Briumvi (ublituximab) is a monoclonal antibody, a type of drug developed to attack specific targets in the immune system. The drug binds to a marker (CD20) on the surface of B cell 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. Targeted B cells are destroyed. This reduces the chance of a relapse, relieves symptoms and slows down the progression of the disease[#]

Who should take ublituximab (Briumvi)?

Briumvi is used for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease

Who should not take ublituximab (Briumvi)?

Contraindications

You should not take Briumvi if you are allergic to ublituximab or any of the other ingredients of the medicine. You should not take Briumvi if you are suffering from a severe infection, if you have cancer or if you have severe problems with your immune system.

You may not be offered Briumvi if you have had hepatitis B, because medicines like Briumvi can cause the hepatitis B virus to become active again.

Conception and pregnancy

If you are able to become pregnant, you should use contraception while taking Briumvi and for 4 months after your last infusion.

Tell your doctor before you take Briumvi if you are pregnant, think you may be pregnant or are planning to have a baby.

How is ublituximab (Briumvi) administered?

Briumvi is given as an intravenous infusion (drip) in a hospital or clinic. The first infusion is given on day 1 and the second dose is given 2 weeks later. Subsequent infusions are given every 24 weeks. Each infusion takes 1 hour except the first one which takes 4 hours.

When you take Briumvi, your infusion team will give you other medicines such as an antihistamine and a corticosteroid. This is to reduce the risk of infusion related reactions such as fever or a rash. They will monitor your health during and after the infusion.

What are the side effects from taking ublituximab (Briumvi)?

The most common side effect reported in phase III clinical studies were infusion-related reactions. These are a type of allergic reaction which may develop while a medicine is given or up to 24 hours afterwards.

In trials for Briumvi, these were common, affecting more than 1 in 10 people. The reactions were mostly mild to moderate in severity and were most frequent after the first infusion and decreased significantly from the second infusion onwards. Your infusion team will give you other medicines each time to reduce the risk of having an infusion related reaction. You will also be monitored carefully.

Other side effects listed on the Patient Information Leaflet include:

Increased risk of infections

- More than 1 in 10 people taking Briumvi may have respiratory infections (nose, throat or airways)
- Up to 1 in 10 people taking Briumvi may have chest or lung infections or herpes infections (cold sores or shingles).

Neutropenia (low levels of a white blood cell type called neutrophils)
Pain in your arms or legs. These may affect up to 1 in 10 people who take Briumvi.

Progressive multifocal leukoencephalopathy (PML) is a very rare and life-threatening brain infection. Although no-one taking Briumvi has developed PML, it is potential risk. You should alert your neurologist if you notice new or worsening symptoms.

A full list of side effects is included in the manufacturer's patient information sheet which is available from Medicines.ie.

What are the findings from ublituximab (Briumvi) clinical trials?

In two phase III studies, 1094 participants with relapsing remitting MS took either Briumvi or Aubagio (teriflunomide) for 96 weeks. Treatment with ublituximab resulted in a median reduction of 97% of CD19+ B cell counts from baseline values after the first infusion in both studies and remained depleted at this level for the duration of dosing Compared to Aubagio, Briumvi reduced relapse rate by over 59% in Ultimate 1 and 49% in Ultimate 2. Briumvi also significantly reduced the number of active lesions compared to Aubagio. Significantly more people taking Briumvi achieved NEDA (no evidence of disease activity). There was no significant difference between the two treatments in the number of participants with 12 or 24 week confirmed disability progression; however, significantly more participants taking Briumvi had 12 and 24 week confirmed disability improvement.

Further details of ULTIMATE I
Further details of ULTIMATE II

When was ublituximab (Briumvi) made available?

15*th* January 2025.

Is ublituximab (Briumvi) reimbursed?

Briumvi is currently reimbursed for those with relapsing forms of MS (RMS) with active disease.

References:

All information available from BRIUMVI®, Summary of Product Characteristics available at https://www.ema.europa.eu/en/documents/product-information/briumvi-epar-product-information_en.pdf. Last accessed March 2025

Steinman L, et al. NEJM 2022;387(8):704–14