swissmedic

Summary report on authorisation dated 3 June 2025

Briumvi® (active substance: ublituximab)

Authorisation in Switzerland: 6 February 2025

Concentrate for solution for infusion for the treatment of adults with relapsing forms of multiple sclerosis with active disease

Information on authorisation

Briumvi contains the active substance ublituximab. Briumvi is used in adult patients with relapsing forms of multiple sclerosis (MS) with active disease. The active disease is defined by clinical findings or imaging features, which means that these patients experience relapses and/or show active signs of inflammation on their scans.

MS is a chronic disease of the central nervous system (brain and spinal cord) that is caused primarily by an incorrectly regulated immune system response. What are termed B cells attack the protective sheath surrounding the nerve fibres in particular. This can lead to inflammation and long-term damage to the nerves. Ublituximab is a monoclonal antibody (a type of protein) that was developed in order to recognise and bind to a specific marker (CD20) on the surface of these B cells, causing these "dysregulated" cells to be selectively disabled. This helps to reduce the disease activity and thereby prevent disease flares.

About 2.8 million people worldwide are affected by MS, including around 18,000 in Switzerland. Their number is growing. Women are two to three times more frequently affected than men.

In deciding whether to authorise the medicinal product Briumvi, Swissmedic took into account the assessments of the European Medicines Agency (EMA/173313/2023) and the US Food and Drug Administration (FDA), and the corresponding product information texts.

Since the assessment of the clinical data was based on the assessment reports of these foreign authorities, the preconditions for a full SwissPAR (Swiss Public Assessment Report – a detailed report for professionals) and a resulting Summary report on authorisation are not met. Swissmedic refers to the authorisation of the foreign reference authorities.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Briumvi®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.