

# Briumvi

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using Briumvi?

Briumvi contains the active ingredient ublituximab. Briumvi is used to treat adults with relapsing forms of multiple sclerosis (RMS), where the patient has flare-ups (relapses) followed by periods with milder or no symptoms.

For more information, see Section [1. Why am I using Briumvi?](#) in the full CMI.

### 2. What should I know before I use Briumvi?

Do not use if you have ever had an allergic reaction to ublituximab or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Briumvi?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Briumvi and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Briumvi?

- Briumvi will be given to you by a doctor or a nurse. Briumvi must be diluted before it is given to you. Dilution will be done by a healthcare professional. It will be given as an infusion into a vein (intravenous infusion).
- You will be closely monitored while you are being given Briumvi and for at least 1 hour after the first two infusions have been given. This is in case you have any side effects such as infusion-related reactions.

More instructions can be found in Section [4. How do I use Briumvi?](#) in the full CMI.

### 5. What should I know while using Briumvi?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Briumvi.</li><li>• Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular, chemotherapy, immunosuppressants (except corticosteroids) or other medicines used to treat multiple sclerosis.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use Briumvi if you are suffering from a severe infection, if you have been told that you have severe problems with your immune system, or if you have cancer.</li><li>• Do not use Briumvi if you are pregnant unless you have discussed this with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Briumvi is unlikely to affect your ability to drive and use machines.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• This medicine is to be stored in a refrigerator (2 °C - 8 °C). It is not to be frozen. The vial is to be kept in the outer carton in order to protect from light.</li><li>• It is recommended that the product is used immediately after dilution.</li></ul>

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

### 6. Are there any side effects?

Tell your doctor or nurse straight away if you experience any signs or symptoms of an infusion-related reaction during the infusion or up to 24 hours after the infusion. Symptoms can include, but are not limited to itchy skin, hives, redness of the face or skin, throat irritation, trouble breathing, swelling of tongue or throat, wheezing, chills, fever, headache, dizziness, feeling faint, nausea, abdominal (belly) pain and rapid heartbeat.

Tell your doctor or nurse straight away if you notice any of these signs of infection, fever or chills, cough which does not go away and/ or herpes (such as cold sore, shingles or genital sores)

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# Briumvi

Active ingredient(s): *ublituximab*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Briumvi. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Briumvi.**

Where to find information in this leaflet:

- [1. Why am I using Briumvi?](#)
- [2. What should I know before I use Briumvi?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Briumvi?](#)
- [5. What should I know while using Briumvi?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Briumvi?

**Briumvi contains the active ingredient ublituximab.**

Briumvi is a type of protein called a monoclonal antibody. Antibodies work by attaching to specific targets in your body.

**Briumvi is used to treat adults with relapsing forms of multiple sclerosis (RMS), where the patient has flare-ups (relapses) followed by periods with milder or no symptoms.**

Multiple Sclerosis (MS) affects the central nervous system, especially the nerves in the brain and spinal cord. In MS, white blood cells called B cells that are part of the immune system (the body's defence system) work incorrectly and attack a protective layer (called myelin sheath) around nerve cells, causing inflammation and damage. Breakdown of the myelin sheath stops the nerves from working properly and causes symptoms of MS. Symptoms of MS depend on which part of the central nervous system is affected and can include problems with walking and balance, muscle weakness, numbness, double vision and blurring, poor coordination, and bladder problems.

In relapsing forms of MS, the patient has repeated attacks of symptoms (relapses) that can appear suddenly within a few hours, or slowly over several days. The symptoms disappear or improve between relapses, but damage may build up and lead to permanent disability.

Briumvi works by attaching to a target called CD20 on the surface of B cells. B cells are a type of white blood cell which are part of the immune system. In multiple sclerosis, the immune system attacks the protective layer around nerve cells. B cells are involved in this process. Briumvi targets and removes the B cells and thereby reduces the

chance of a relapse, relieves symptoms and slows down the progression of the disease.

## 2. What should I know before I use Briumvi?

### Warnings

**Do not use Briumvi if:**

- you are allergic to ublituximab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Do not use Briumvi if you are suffering from a severe infection, if you have been told that you have severe problems with your immune system, or if you have cancer.
- Do not use Briumvi if you are pregnant unless you have discussed this with your doctor.

**Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition
- have an infection. Your doctor will wait until the infection is resolved before giving you Briumvi.
- have ever had hepatitis B or are a carrier of the hepatitis B virus. This is because medicines like Briumvi can cause the hepatitis B virus to become active again. Before your Briumvi treatment, your doctor will check if you are at risk of hepatitis B infection. Patients who have had hepatitis B or are carriers of the hepatitis B virus will have a blood test and will be monitored by a doctor for signs of hepatitis B infection.
- have recently been given any vaccine or might be given a vaccine in the near future.
- have cancer or if you have had cancer in the past. Your doctor may decide to delay your treatment.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

### Infusion-related reactions

- To reduce the risk of infusion-related reaction, your doctor will give you other medicines before each infusion of Briumvi (see Section 4. [How do I use Briumvi?](#)) and you will be closely monitored during the infusion.
- If you get an infusion reaction, your doctor may need to stop or slow down the rate of infusion.

## Infections

- Talk to your doctor before you are given Briumvi if you have or think you have an infection. Your doctor will wait until the infection is resolved before giving you Briumvi.
- You might get infections more easily with Briumvi. This is because the immune cells that Briumvi targets also help to fight infection.

## Vaccinations

- Tell your doctor if you have recently been given any vaccine or might be given a vaccine in the near future.
- Your doctor will check if you need any vaccinations before you start your treatment with Briumvi. You should receive a type of vaccine called a live or live attenuated vaccines at least 4 weeks before you start treatment with Briumvi. While you are being treated with Briumvi, you should not be given live or live attenuated vaccines until your doctor tells you that your immune system is no longer weakened.
- When possible, you should receive other types of vaccine called inactivated vaccines at least 2 weeks before you start treatment with Briumvi. If you would like to receive any inactivated vaccines while you are being treated with Briumvi, talk to your doctor.

## Pregnancy and breastfeeding

Check with your doctor if you are pregnant, think that you might be pregnant or intend to become pregnant. This is because Briumvi may cross the placenta and affect your baby.

Do not use Briumvi if you are pregnant unless you have discussed this with your doctor. Your doctor will consider the benefit of you taking Briumvi against the risk to your baby.

If you have a baby and you received Briumvi during your pregnancy, it is important to tell your baby's doctor about receiving Briumvi so they can recommend when your baby should get vaccinated.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether Briumvi passes into your breast milk.

## Use in children and adolescents

- Briumvi is not intended to be used in children and adolescents under 18 years old. This is because it has not yet been studied in this age group.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

### Some medicines may interfere with Briumvi and affect how it works.

Tell your doctor if you are taking, have recently taken or might take medicines that affect your immune system,

such as chemotherapy, immunosuppressants (except corticosteroids) or other medicines used to treat MS. This is because these may have an added effect on the immune system.

If you plan to have any vaccinations (see Section 2. [What should I know before I use Briumvi?](#) above)

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Briumvi.**

## 4. How is Briumvi given?

### How much Briumvi is given?

- The first dose of Briumvi will be 150 mg. This infusion will last 4 hours.
- The second dose of Briumvi will be 450 mg given 2 weeks after the first dose. This infusion will last 1 hour.
- Subsequent dosing of Briumvi will be 450 mg given 24 weeks after the first dose and every 24 weeks thereafter. These infusions will last 1 hour

### How Briumvi is given

- Before you are given Briumvi, you will receive other medicines to prevent or reduce possible side effects such as infusion-related reactions (see Sections 2. [What should I know before I use Briumvi?](#) and 6. [Are there any side effects?](#) for information about infusion-related reactions). You will receive a corticosteroid and an antihistamine before each infusion and you may also receive other medicines to reduce fever.
- Briumvi will be given to you by a doctor or a nurse. Briumvi must be diluted before it is given to you. Dilution will be done by a healthcare professional. It will be given as an infusion into a vein (intravenous infusion).
- You will be closely monitored while you are being given Briumvi and for at least 1 hour after the first two infusions have been given. This is in case you have any side effects such as infusion-related reactions. The infusion may be slowed, temporarily stopped, or permanently stopped if you have an infusion-related reaction, depending on how serious it is (see Sections 2. [What should I know before I use Briumvi?](#) and 6. [Are there any side effects?](#) for information about infusion-related reactions).

### If you miss an infusion of Briumvi

- If you miss an infusion of Briumvi, talk to your doctor to arrange to have it as soon as possible. Do not wait until your next planned infusion.
- To get the full benefit of Briumvi, it is important that you receive each infusion when it is due.

### If you are given too much Briumvi

This medicine will be given to you by your doctor or nurse. In the unlikely event that you are given too much (an overdose) your doctor or nurse will check you for side effects.

In the unlikely event you are not with a healthcare professional, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using Briumvi?

### Things you should do

- Tell your partner or carer about your Briumvi treatment. They might notice symptoms of progressive multifocal leukoencephalopathy (PML see following) that you do not, such as memory lapses, trouble thinking, difficulty walking, sight loss, changes in the way you talk, which your doctor may need to investigate.
- Tell your doctor if you are planning to become pregnant.
- If you are able to become pregnant (conceive), you must use contraception during treatment with Briumvi and for at least 4 months after your last infusion of Briumvi.

### Call your doctor straight away if you:

- have or think you may have any infusion-related reaction (See Section 6. [Are there any side effects?](#)). Infusion related reactions can happen during the infusion or up to 24 hours after the infusion.
- have an infection or any of the following signs of infection during or after Briumvi treatment: fever or chills, cough that does not go away, and/ or herpes (such as cold sore, shingles or genital sores)
- have a headache with fever, neck stiffness, sensitivity to light, nausea, confusion, seizures, personality change, incoordination (ataxia), altered consciousness and/or coma. These may be symptoms of an infection of the lining around the brain and spine (meningitis), an infection of the brain (encephalitis) or both (meningoencephalitis), which can be fatal.
- think your MS is getting worse or if you notice any new symptoms. This is because of a very rare and life-threatening brain infection, called 'progressive multifocal leukoencephalopathy' (PML), which can cause symptoms similar to those of MS. PML can occur in patients taking medicines like Briumvi, and other medicines used for treating MS.

Remind any doctor, dentist or pharmacist you visit that you are using Briumvi.

### Things you should not do

- Your doctor will tell you how long you need to receive Briumvi. Do not stop treatment with Briumvi unless your doctor tells you to.

- You should not be given live or live attenuated vaccines until your doctor tells you that your immune system is no longer weakened.

### Driving or using machines

Briumvi is unlikely to affect your ability to drive and use machines.

### Looking after your medicine

- Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.
- It is recommended that the product is used immediately after dilution. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the healthcare professional and would normally not be longer than 24 hours at 2 °C - 8°C and subsequently 8 hours at room temperature
- Store at 2°C to 8°C (Refrigerate. Do not freeze)
- Keep vial in the outer carton to protect from light.
- Do not shake

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

Do not throw away any medicines via wastewater or household waste. Your doctor or nurse will throw away any medicines that are no longer being used. These measures will help protect the environment.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Musculoskeletal and connective tissue disorders:</b> <ul style="list-style-type: none"><li>• Pain in extremity (arms or legs)</li></ul> <b>Infections:</b> <ul style="list-style-type: none"><li>• upper respiratory tract infections (nose and throat infections)</li><li>• respiratory tract infections (infection of the airways)</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<ul style="list-style-type: none"> <li>• lower respiratory tract infections (infection of the lungs such as bronchitis or pneumonia)</li> <li>• herpes infections (cold sore or shingles)</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<p><b>Infusion-related reactions:</b></p> <ul style="list-style-type: none"> <li>• itchy skin</li> <li>• hives</li> <li>• redness of the face or skin</li> <li>• throat irritation</li> <li>• trouble breathing</li> <li>• swelling of tongue or throat</li> <li>• wheezing</li> <li>• chills</li> <li>• fever</li> <li>• headache</li> <li>• dizziness</li> <li>• feeling faint</li> <li>• nausea</li> <li>• abdominal (belly) pain</li> <li>• Rapid heartbeat</li> </ul> <p><b>Infections:</b></p> <ul style="list-style-type: none"> <li>• fever or chills</li> <li>• cough which does not go away</li> <li>• herpes (such as cold sore, shingles or genital sores)</li> <li>• headache with fever, neck stiffness, sensitivity to light, nausea, confusion, seizures, personality change, incoordination (ataxia), altered consciousness and/or coma. These may be symptoms of an infection of the lining around the brain and spine (meningitis), an infection of the brain (encephalitis) or both (meningoencephalitis), which can be fatal.</li> </ul> <p><b>Blood and lymphatic system disorders:</b></p> <ul style="list-style-type: none"> <li>• Neutropenia (low levels of neutrophils, a type of white blood cell)</li> </ul> <p><b>Hepatobiliary disorders:</b></p> <ul style="list-style-type: none"> <li>• Dark coloured urine or yellowing of your skin and eyes</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Briumvi contains

<b>Active ingredient (main ingredient)</b>	Ublituximab
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride Sodium citrate Polysorbate 80 Hydrochloric acid (for pH adjustment) Water for injections
<b>Potential allergens</b>	Not applicable

**Do not use this medicine if you are allergic to any of these ingredients.**

### What Briumvi looks like

Briumvi is clear to opalescent, and colourless to slightly yellow solution. It is supplied as a concentrate for solution for infusion.

This medicine is available in packs containing 1 vial, and 3 vials (glass vial of 6 ml concentrate)

Aust R 453648.

### Who distributes Briumvi

Accelagen Pty Ltd.  
Suite 2.02  
785 Toorak Road  
Hawthorn East, Victoria, Australia 3123  
E-mail: [info@accelagen.com.au](mailto:info@accelagen.com.au)

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