BRIUMVI® (ublituximab)▼
150 mg/6 mL injection for IV

A guide for people with relapsing remitting multiple sclerosis (RRMS)

This guide has been developed by Neuraxpharm for patients with RRMS who have been prescribed BRIUMVI®.
The information in this guide is not intended to replace the advice of your healthcare professional or the patient information leaflet.

Contents

Welcome

Chapter 1

You have been given this booklet because you have been prescribed BRIUMVI®, a treatment for RRMS.[1]

Starting a new treatment can be daunting, but when you understand your treatment, you can make more confident, informed choices about your health.

BRIUMVI® is prescribed for the treatment of RRMS because in clinical trials it was shown to be effective at **reducing relapses** and symptoms.[2,3]

This guide is to help you:

- get the most out of your BRIUMVI® treatment
- find information, advice, and support
- feel empowered to contribute to decisions about your care.

Everyone's multiple sclerosis (MS) journey is different[4,5]

If you have any questions about MS, BRIUMVI®, or your care, speak to a member of your healthcare team for personalised advice.

Understanding relapsing remitting multiple sclerosis (RRMS)

Chapter 2

What is RRMS?

MS is a chronic inflammatory disease of the central nervous system. The central nervous system includes the brain, spinal cord, and optic nerves (in the eyes).[4,6]

In many cases, MS flares up sometimes and then eases off – this is called relapsing remitting MS.[4,6]

MS is an autoimmune disease

The body has an immune system, which helps to protect it from infection. However, sometimes the immune system mistakenly attacks the body's own tissues, and this is known as an autoimmune disease.[7]

Structure of a nerve fibre

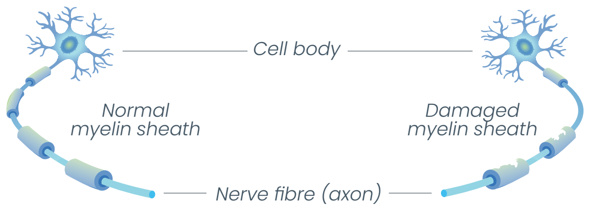

Image created by Neuraxpharm, UK.

Nerve fibres carry messages within your body's central nervous system. In MS, immune (defence) cells known as T cells and B cells gradually destroy the protective coating of the nerve fibres. This protective coating is called the myelin sheath. It ensures that signals from the brain travel quickly and easily along the nerve fibre. If the myelin sheath is damaged, these signals are interrupted or slowed down.[4,6]

When the signals to and from the brain, spinal cord, and optic nerves are interrupted, it can cause symptoms including:[4,5,8,9]

- sensory issues like numbness/tingling
- visual problems like pain when moving your eyes
- muscle problems like shaking, bladder problems, and balance problems
- cognitive difficulties like tiredness, poor memory, and difficulty thinking.

What causes MS?

The causes of MS are not yet fully understood, but current research suggests that genetics and other unknown factors may play a role. Lifestyle factors include things like smoking, exposure to ultraviolet light, and being very overweight can also increase the risk of developing MS. It is important to remember that you didn't 'cause' your MS. It is a complex condition with lots of factors you cannot control.[6,10,11]

Treating MS

Chapter 3

What does MS treatment aim to do?

At the moment, there is no cure for MS. However, there are a number of treatment options that can help to:[6,9]

- prevent or reduce relapses
- reduce inflammation during a relapse (flare-up of symptoms)
- slow down the progression of the disease
- prolong the times in remission (time without symptoms)
- relieve symptoms
- reduce the risk of complications
- preserve your quality of life.

What treatment options are available and what are they used for?

Several **medical treatments** can be used to:[4,9,12]

- address specific symptoms, e.g. pain, muscle spasms, or bowel problems
- reduce inflammation
- slow down disease progression.

In addition, there are many other treatment options that can work **alongside medical treatment** to help improve your quality of life, e.g.:

- physiotherapy to improve stiffness, muscle cramps, pain, mobility, balance, and posture[12–14]
- occupational therapy, which helps you keep on top of everyday activities[14]
- psychotherapy, such as cognitive behavioural therapy or acceptance and commitment therapy, to deal with mental and emotional difficulties[14,15]
- relationship and sexual therapy[14]
- speech and language therapy to overcome difficulties with talking, eating, and drinking[16]
- cognitive rehabilitation therapy to help with memory and concentration[14,17]
- complementary therapies such as reflexology, yoga, aromatherapy, acupuncture, massage etc., which many people find help them to relax.[18]

Speak to your healthcare team to find out more about these treatments.

About BRIUMVI®

Chapter 4

Your healthcare professional has prescribed BRIUMVI®, an infusion that's used to slow down the progression of MS.[1]

What is BRIUMVI®?

BRIUMVI® contains the drug ublituximab and it is given as an intravenous (IV) infusion (drip). The first time you have BRIUMVI®, it usually takes around 4 hours. The first treatment is given slowly at a lower dose to check that your body can tolerate the treatment. The next time you have the treatment, the full dose is given at a faster rate, so it takes around 1 hour.[1]

The second infusion is 2 weeks after the first. After that, infusions will be given every 24 weeks (see below).[1]

Day 1 — approx. 4h[a]

First infusion
150 mg 1-hour post-infusion monitoring

Day 15 — approx. 1h[a]

Second infusion (2 weeks after the first infusion)
450 mg 1-hour post-infusion monitoring

Subsequent infusions — approx. 1h[a]

Every 24 weeks thereafter[b]
450 mg No **systematic** post-infusion monitoring required from the third infusion onwards[c]

How does BRIUMVI® work?

Ublituximab is a synthetic protein that mimics the action of human antibodies in the immune system. It is called a monoclonal antibody because it attaches itself to **one** specific target.[1,6]

In MS, B cells from the immune system attack the body's own tissues by mistake. The B cells carry a specific protein called CD20, which acts like a marker or target. BRIUMVI® identifies this specific protein and attaches itself to the B cells that have the marker on them.[1,6]

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[a] Infusion time may vary if it needs to be paused or slowed down.
[b] The second dose is given 2 weeks after the first, then every 24 weeks.
[c] After your infusion: if you've had a reaction before, you'll be monitored for an hour afterwards.

Once the BRIUMVI® antibodies have attached themselves to the damaged B cells, they destroy the cells to prevent them doing any more damage to the body's tissues. This helps to relieve some of the symptoms of MS, to reduce the number of relapses, and to slow the progression of the disease.[1]

How long does BRIUMVI® treatment last?

Your healthcare professional will continue to prescribe BRIUMVI® for as long as you benefit from it. There is no limit to how long you can have BRIUMVI® for.[1]

Tell your treatment team in good time if you feel unwell before your infusion appointment. You may need to arrange an alternative appointment for when you feel better.

What does my healthcare professional need to know before I start treatment with BRIUMVI®?

Before treatment with BRIUMVI®, your healthcare professional needs to know if you:[1]

- have or think you may have an infection at the moment
- have ever had a hepatitis B infection
- have recently been vaccinated or are planning to be in the near future
- have or have had cancer
- are pregnant or are planning to have children.

If you're taking any other medicines, including those bought over the counter without prescription, supplements, or complementary products, then you should tell your healthcare professional.

Will the side effects stop if I stop having BRIUMVI®?

If you discontinue treatment, some side effects may persist or appear until the number of B cells has returned to normal.[1]

What do I need to know before taking BRIUMVI®?

Women who want to have children need to know that BRIUMVI® is able to cross the placental barrier and may affect your baby.[1]

If you are able to get pregnant, you need to use effective contraception during treatment with BRIUMVI® and for at least 4 months after your last BRIUMVI® infusion.[1]

If you are pregnant, if you think you are pregnant, or if you are planning a pregnancy, you should inform your treatment team. Your healthcare professional will weigh up with you the benefits of treatment against the risks to your child.[1]

If you have a child, and were being treated with BRIUMVI® during your pregnancy, you should inform your child's healthcare professional.

It is not known whether BRIUMVI® passes into your breast milk. Talk to your healthcare professional about the best way to feed your baby if you take BRIUMVI®.[1]

What are the possible side effects of BRIUMVI®?

Like all medicines, BRIUMVI® may cause side effects. These can be related to the treatment itself, or, more often, to the infusion process.[1]

Infusion-related reactions are a type of allergic reaction that may happen during the infusion and for up to 24 hours afterwards. Sometimes they can be serious, which is why you will be closely monitored during and after your first and second infusions.[1]

Treatment-related side effects

Your immune system helps to protect you from infections. One part of your immune system is the B cells. BRIUMVI® destroys B cells that attack your own body's tissues, but in doing so, your overall immune system is weakened. This is why you are more likely to get an infection during treatment with BRIUMVI®.[1]

Possible symptoms of an infusion-related reaction (very common: may affect more than 1 in 10 people) **include:**[1]

- chills
- headache
- feeling sick
- throat irritation
- swelling of the tongue or throat
- increased heart rate
- itchy skin
- fever
- breathing problems/wheezing
- stomach pain
- redness of the face or skin
- feeling faint
- dizziness

For more information on side effects and other safety information, please refer to the patient information leaflet.

If you notice any of these signs of infection, tell your healthcare professional immediately:

- fever or chills
- a cough that doesn't go away
- herpes (cold sores, shingles, genital sores).

Alerting your healthcare team to infections doesn't necessarily mean that they will stop your treatment, but your BRIUMVI® treatment may need to be paused until the infection has cleared.[1]

Other side effects that could happen during treatment include:[1]

- respiratory tract infections
- herpes virus infections
- neutropenia (low levels of certain types of white blood cells): your blood count will need to be monitored throughout your treatment with BRIUMVI® to check for neutropenia
- pain in the arms or legs.

Reporting of side effects

This medicine is subject to additional monitoring ▼. This will allow quick identification of new safety information. If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at **www.mhra.gov.uk/yellowcard** or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

Getting the most out of your BRIUMVI® treatment

Chapter 5

Get organised

Make a note of doctor's appointments and infusion appointments on a calendar or in a diary, and set reminders on your phone.

Write down any questions, thoughts, or concerns you have, and take these notes to your appointment so that you can discuss them with your healthcare team.

You may need to book time off work to go to appointments, so remember to let your workplace know in advance so you can attend your appointments.

What to expect at your infusion appointment

BRIUMVI® is always administered as an IV drip by a healthcare professional.[1]

Before the infusion, you may be given other medicines to help prevent any possible side effects. These include a corticosteroid to reduce inflammation, an antihistamine to reduce allergic reactions, and possibly paracetamol or something similar to help prevent a high temperature.[1]

The medical staff will put in a cannula. This is a needle that is placed in a vein. The BRIUMVI® is a liquid that will be fed slowly through a tube into the cannula and into your vein.

Once the infusion is finished, the cannula will need to be removed before you go home. You may have a dressing on the area of skin where your cannula was for a day or two.

For at least the first two doses, you will be closely monitored by your healthcare team during the infusion and for 1 hour afterwards, in case you get any side effects or infusion-related reactions. If this happens, depending how severe the reaction is, the infusion may be slowed down, paused for a while, or stopped.[1]

What to do if you miss an infusion

BRIUMVI® needs to be given regularly. It is important that you attend every infusion appointment at the scheduled time to get the best results from the treatment. Interruptions to the treatment schedule can increase your risk of a flare-up (relapse) of symptoms.[1]

If you have missed an infusion, speak to your healthcare professional so that another appointment can be arranged as soon as possible. Do not wait until the next scheduled appointment.[1]

What to take to your infusion appointment

Warm layers

The first infusion is usually given over approximately 4 hours, and subsequent infusions usually take around 1 hour.[1] You will need to sit or lie still for this time and you may easily get cold, so bring warm clothing or a blanket with you. Wear loose, comfortable clothing and make sure your arms, where the cannula will be inserted, can be easily accessed.

Something to do

It's also a good idea to have something to entertain you during the infusion. Bring a book, puzzle, or some headphones so you can listen to music or a podcast. If you are planning to use your phone, make sure you have enough battery power to last for the full length of the appointment. You may not be able to charge your phone while having your infusion. Bring your charger anyway, and ask the staff on the unit if that's allowed.

Snacks and drinks

Bring some snacks that are easy to carry and easy to eat, like nuts, fruit, or a sandwich. Staying hydrated during your infusion can help you to stay comfortable. Bring a drink with a sealable lid, like a bottle of water.

Home comforts

If you have a favourite pair of slippers, dressing gown, or soft toy, there's nothing to stop you bringing these small home comforts with you to make your experience more comfortable.

What to do if you are nervous about your infusion

It can be daunting if you are new to IV treatment, and some people aren't comfortable with hospitals or needles. It's normal to feel a little nervous or worried before your infusion.

To ease your worries, why not try some or all of the following:

- talk about your fears with a loved one, a healthcare professional, or someone with MS who has been through a similar experience and can help to reassure you
- ask questions – reaching out to your healthcare team with any questions that you may have can help you to feel more prepared
- plan a treat for yourself for after the appointment so that you have something positive to focus on and look forward to; it could be nice meal, a coffee, or just time to indulge in a favourite hobby
- use mindfulness, meditation, or controlled breathing to relax your body and clear your mind of unwanted thoughts; deep breaths and relaxation exercises can help you to stay calm.

Finding support and information about MS

Chapter 6

There are a number of websites where you can find trustworthy information and advice about all aspects of MS. Some of these are listed below.

The **MS Society** offers support, advice, and information for everyone affected by MS, with lots of events, resources, and news.

mssociety.org.uk

Shift.ms is the digital community that helps people with MS connect and manage their health, from diagnosis.

shift.ms
or download from the app stores

The **Multiple Sclerosis Trust** is a charity for everyone with MS. Their website offers comprehensive information, plus ways to get involved.

mstrust.org.uk

The Brain Charity supports anyone affected by neurological conditions like MS with information and helpful resources.

thebraincharity.org.uk

MS-UK supports people living with MS, by providing information and support we empower them to make choices about how they can live better.

ms-uk.org

The **NHS** offers clear, plain language information about MS, its symptoms, and its treatment.

nhs.uk/conditions/multiple-sclerosis

Chapter 7

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NEURAXPHARM®
Your CNS specialist

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