Infusion Rate Card

briumvi
ublituximab-xiiy 150 mg/6 mL injection for IV

Dilute Briumvi into an infusion bag containing 0.9% NaCl injection, USP.*
See accompanying full Prescribing Information for full Dosing and Administration instructions.

Administer BRIUMVI under the close supervision of an experienced healthcare professional with access to appropriate medical support to manage severe reactions such as serious infusion reactions.

FIRST INFUSION

BRIUMVI dose	150 mg
Total volume	250 mL
Infusion Rate	
0-30 min	10 mL/hr
30 min-hour 1	20 mL/hr
Hours 1-2	35 mL/hr
Hours 2-4	100 mL/hr
Total infusion time†	4 hours

SECOND INFUSION

2 weeks after the first infusion

BRIUMVI dose	450 mg
Total volume	250 mL
Infusion Rate	
0-30 min	100 mL/hr
30 min-hour 1	400 mL/hr
Total infusion time†	1 hour

SUBSEQUENT INFUSIONS

Once every 24 weeks. First subsequent infusion administered 24 weeks after the first infusion

BRIUMVI dose	450 mg
Total volume	250 mL
Infusion Rate	
0-30 min	100 mL/hr
30 min-hour 1	400 mL/hr
Total infusion time†	1 hour

- Premedicate with a **corticosteroid** and an **antihistamine** administered orally or intravenously approximately **30-60 minutes** prior to each infusion to reduce the frequency and severity of infusion reactions. The addition of an antipyretic may also be considered
- Observe the patients during infusion and for at least 1 hour after the first 2 infusions. Post-infusion monitoring of subsequent infusions is at physician discretion unless infusion reaction and/or hypersensitivity has been observed in association with the current or any prior infusion

*No incompatibilities between BRIUMVI and polyvinyl chloride (PVC) or polyolefin (PO) bags and intravenous (IV) administration sets have been observed.
†Infusion duration may take longer if the infusion is interrupted or slowed.
USP, United States Pharmacopeia.

This Infusion Rate Card is not a substitute for the full Prescribing Information.
Please see selected Important Safety Information and accompanying full Prescribing Information.

Rate modifications in response to infusion reactions depend on the severity

MILD TO MODERATE

Reduce the infusion rate to half the rate at the onset of the infusion reaction and maintain the reduced rate for at least 30 minutes. If this rate is tolerated, increase the rate as described in the Administration and Infusion Rate Table. This change in rate will increase the total duration of the infusion but not the total dose.

SEVERE

Immediately interrupt the infusion and administer appropriate supportive treatment, as necessary. Restart the infusion only after all symptoms have resolved.

When restarting, begin at **half of the infusion rate at the time of onset of the infusion reaction**. If this rate is tolerated, increase the rate as described in the Administration and Infusion Rate Table. This change in rate will increase the total duration of the infusion but not the total dose.

LIFE-THREATENING

Immediately stop infusion and permanently discontinue BRIUMVI if there are signs of a life-threatening or disabling infusion reaction.

Provide appropriate supportive treatment.

INDICATION

BRIUMVI is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

IMPORTANT SAFETY INFORMATION

Contraindications: BRIUMVI is contraindicated in patients with active hepatitis B virus infection and a history of life-threatening infusion reaction to BRIUMVI.

WARNINGS AND PRECAUTIONS

Infusion Reactions: BRIUMVI can cause infusion reactions, which can include pyrexia, chills, headache, influenza-like illness, tachycardia, nausea, throat irritation, erythema, and an anaphylactic reaction.

Observe treated patients for infusion reactions during the infusion and for at least one hour after the completion of the first two infusions unless infusion reaction and/or hypersensitivity has been observed in association with the current or any prior infusion. Inform patients that infusion reactions can occur up to 24 hours after the infusion. Administer the recommended pre-medication to reduce the frequency and severity of infusion reactions. If life-threatening, stop the infusion immediately, permanently discontinue BRIUMVI, and administer appropriate supportive treatment.

Infections: Delay BRIUMVI administration in patients with an active infection until the infection is resolved.

Vaccinations: Administer all immunizations according to immunization guidelines: for live or live-attenuated vaccines at least 4 weeks and, whenever possible at least 2 weeks prior to initiation of BRIUMVI for non-live vaccines.

Fetal Risk: A pregnancy test is recommended in females of reproductive potential prior to each infusion.

Reduction in Immunoglobulins: Monitor the levels of quantitative serum immunoglobulins during treatment, especially in patients with opportunistic or recurrent infections, and after discontinuation of therapy until B-cell repletion.

Most Common Adverse Reactions: The most common adverse reactions in RMS trials (incidence of at least 10%) were infusion reactions and upper respiratory tract infections.

Reference: BRIUMVI [prescribing information]. New York, NY: TG Therapeutics, Inc.; 2022.

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TG Therapeutics

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