

BKEMV[®] PRODUCT FACT SHEET

INDICATIONS

BKEMV[®] (eculizumab-aeeb) is indicated for the treatment of:

- patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
- patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
- generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

BKEMV is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).



PRODUCT INFORMATION

NDC	Description	Quantity
55513-180-01	300 mg of BKEMV in 30 mL (10 mg/mL)	One single-dose vial per carton

STORAGE AND HANDLING REQUIREMENTS

Store BKEMV vials refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use. BKEMV vials may be stored in the original carton at controlled room temperature (not more than 25°C (77°F)) for only a single period up to 7 days. Do not use beyond the expiration date stamped on the carton. Refer to Prescribing Information for information on the stability and storage of diluted solutions of BKEMV. DO NOT FREEZE. DO NOT SHAKE.

PRODUCT EXPIRATION

The expiration date is printed on each dispensing pack and vial label.

SUPPLIED AND MARKETING BY

Amgen USA Inc.

amgen.com

BKEMV.com

PRODUCT RETURNS

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at 1-800-28-AMGEN (1-800-282-6436). Credit for returns is subject to Amgen's current Product Return Policy.

PRODUCT INFORMATION

Medical Information: 1-800-77-AMGEN (1-800-772-6436)

REIMBURSEMENT INFORMATION

Call Amgen By Your Side at 866-402-5622 Monday to Friday 8:00 am to 5:00 pm CST, or visit <https://www.bkemv.com/support-and-resources>. You may also contact us at BKEMVABYS@amgen.com.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Ecuzumab products, complement inhibitors, increase the risk of serious infections caused by *Neisseria meningitidis*. Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of BKEMV, unless the risks of delaying therapy with BKEMV outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal bacteria in patients receiving a complement inhibitor. See Warnings and Precautions for additional guidance on the management of the risk of serious infections caused by meningococcal bacteria.
- Patients receiving ecuzumab products are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected.

Because of the risk of serious meningococcal infections, BKEMV is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called BKEMV REMS.

Please see additional **Important Safety information** on next page.



IMPORTANT SAFETY INFORMATION (CONT'D)

Contraindications: BKEMV is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection.

Other Infections

Use caution when administering BKEMV to patients with any other systemic infection. Serious infections with *Neisseria* species (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported.

Eculizumab products block terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections with *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. Additionally, *Aspergillus* infections have occurred in immunocompromised and neutropenic patients. Children treated with eculizumab products may be at increased risk of developing serious infections due to *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib). Administer vaccinations for the prevention of *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) infections according to ACIP recommendations. Patients receiving eculizumab products are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

Monitoring Disease Manifestations after BKEMV Discontinuation

Treatment Discontinuation for PNH:

Monitor patients after discontinuing BKEMV for at least 8 weeks to detect hemolysis.

Treatment Discontinuation for aHUS:

After discontinuing BKEMV, monitor patients with aHUS for signs and symptoms of thrombotic microangiopathy (TMA) complications for at least 12 weeks. Clinical signs and symptoms of TMA include changes in mental status, seizures, angina, dyspnea, or thrombosis.

In addition, the following changes in laboratory parameters may identify a TMA complication: occurrence of two, or repeated measurement of any one of the following: a decrease in platelet count by 25% or more compared to baseline or the peak platelet count during BKEMV treatment; an increase in serum creatinine by 25% or more compared to baseline or nadir during BKEMV treatment; or, an increase in serum LDH by 25% or more over baseline or nadir during BKEMV treatment.

If TMA complications occur after BKEMV discontinuation, consider reinstatement of BKEMV treatment, plasma therapy, or appropriate organ-specific supportive measures.

Thrombosis Prevention and Management

The effect of withdrawal of anticoagulant therapy during eculizumab products treatment has not been established. Therefore, treatment with eculizumab products should not alter anticoagulant management.

Infusion-Related Reactions

Administration of eculizumab products may result in infusion-related reactions, including anaphylaxis or other hypersensitivity reactions. In clinical trials, no patients experienced an infusion-related reaction which required discontinuation of eculizumab. Interrupt BKEMV infusion and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur.

Adverse Reactions

The most frequently reported adverse reactions in:

- the PNH randomized trial ($\geq 10\%$ overall and greater than placebo) are: headache, nasopharyngitis, back pain, and nausea
- the aHUS single arm prospective trials ($\geq 20\%$) are: headache, diarrhea, hypertension, upper respiratory infection, abdominal pain, vomiting, nasopharyngitis, anemia, cough, peripheral edema, nausea, urinary tract infections, and pyrexia
- the gMG placebo-controlled clinical trial ($\geq 10\%$) in adult patients is musculoskeletal pain

Drug Interactions

- Concomitant use of eculizumab products with plasma exchange (PE), plasmapheresis (PP), fresh frozen plasma infusion (PE/PI), or in patients with gMG on concomitant IVIg treatment can reduce serum eculizumab product concentrations and requires a supplemental dose of BKEMV.
- Concomitant use of eculizumab products with neonatal Fc receptor (FcRn) blockers may lower systemic exposures and reduce effectiveness of eculizumab products. Closely monitor for reduced effectiveness of BKEMV.

Please see **full Prescribing Information** and **Medication Guide** for BKEMV.

Please visit BKEMV.com for additional information and resources.

Call 1-800-77-AMGEN (1-800-772-6436) if you have questions about the preparation and administration of BKEMV®.

Reference: BKEMV® (eculizumab-aeeb) prescribing information, Amgen.



BKEMV[®]
(eculizumab-aeeb)
Injection for Intravenous Use 300mg/30mL vial