MEDICATION GUIDE

BKEMV® (bee-KEM-vee)
(eculizumab-aeeb)
injection, for intravenous use

What is the most important information I should know about BKEMV?

BKEMV is a medicine that affects your immune system. BKEMV may lower the ability of your immune system to fight infections.

- **BKEMV increases your chance of getting serious meningococcal infections caused by *Neisseria meningitidis* bacteria. Meningococcal infections may quickly become life-threatening or cause death if not recognized and treated early.**
  - You must complete or update your meningococcal vaccine(s) at least 2 weeks before your first dose of BKEMV.
  - If you have not completed your meningococcal vaccines and BKEMV must be started right away, you should receive the required vaccine(s) as soon as possible.
  - If you have not been vaccinated and BKEMV must be started right away, you should also receive antibiotics to take for as long as your healthcare provider tells you.
  - If you had a meningococcal vaccine in the past, you might need additional vaccines before starting BKEMV. Your healthcare provider will decide if you need additional meningococcal vaccines.
  - Meningococcal vaccines do not prevent all meningococcal infections. **Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a serious meningococcal infection:**
    - fever
    - fever with high heart rate
    - headache and fever
    - confusion
    - muscle aches with flu-like symptoms
    - fever and a rash
    - headache with nausea or vomiting
    - headache with a stiff neck or stiff back
    - eyes sensitive to light

Your healthcare provider will give you a Patient Safety Card about the risk of serious meningococcal infection. Carry it with you at all times during treatment and for 3 months after your last dose of BKEMV. Your risk of meningococcal infection may continue for several weeks after your last dose of BKEMV. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

BKEMV is only available through a program called the BKEMV Risk Evaluation and Mitigation Strategy (REMS). Before you can receive BKEMV, your healthcare provider must:

- enroll in the BKEMV REMS program.
- counsel you about the risk of serious meningococcal infections.
- give you information about the signs and symptoms of serious meningococcal infection.
- make sure that you are vaccinated against serious infections caused by meningococcal bacteria and that you receive antibiotics if you need to start BKEMV right away and you are not up to date on your vaccines.
- give you a **Patient Safety Card** about your risk of meningococcal infection, as discussed above.

BKEMV may also increase the risk of other types of serious infections caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria gonorrhoeae*.

- If your child is treated with BKEMV, your child should receive vaccines against *Streptococcus pneumoniae* and *Haemophilus influenzae type b* (Hib).
- Certain people may be at risk of serious infections with gonorrhea. Talk to your healthcare provider about whether you are at risk for gonorrhea infection, about gonorrhea prevention, and regular testing.
- Certain fungal infections (aspergillus) may also happen if you take BKEMV and have a weak immune system or a low white blood cell count.

For more information about side effects, see "**What are the possible side effects of BKEMV?**"

What is BKEMV?

BKEMV is a prescription medicine used to treat:

- people with paroxysmal nocturnal hemoglobinuria (PNH).
- people with atypical hemolytic uremic syndrome (aHUS).
- BKEMV is not for use in treating people with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- adults with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.
- adults with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive.

It is not known if BKEMV is safe and effective in children with PNH or NMOSD.

Who should not receive BKEMV?

Do not receive BKEMV if you have a serious meningococcal infection when you are starting BKEMV treatment.

Before you receive BKEMV, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection or fever.
- are pregnant or plan to become pregnant. It is not known if BKEMV will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if BKEMV passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. BKEMV and other medicines can affect each other causing side effects.

Know the medications you take and the vaccines you receive. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I receive BKEMV?

- Your healthcare provider will give you BKEMV into your vein through an intravenous (IV) line usually over 35 minutes in adults and 1 to 4 hours in children.
- Adults will usually receive a BKEMV infusion:
  - weekly for 5 weeks, then
  - every 2 weeks.
- Children less than 18 years of age, your healthcare provider will decide how often you will receive BKEMV depending on your age and body weight.
- After each infusion, you should be monitored for at least 1 hour for infusion-related reactions. See **"What are the possible side effects of BKEMV?"** If you have an infusion-related reaction during your BKEMV infusion, your healthcare provider may decide to give BKEMV more slowly or stop your infusion.
- If you miss a BKEMV infusion, call your healthcare provider right away.
- **If you have PNH, your healthcare provider will need to monitor you closely for at least 8 weeks after stopping BKEMV. Stopping treatment with BKEMV may cause breakdown of your red blood cells due to PNH.**

  Symptoms or problems that can happen due to red blood cell breakdown include:

  - drop in the number of your red blood cell count
  - kidney problems
  - drop in your platelet counts
  - blood clots
  - confusion
  - difficulty breathing
  - chest pain

- **If you have aHUS, your healthcare provider will need to monitor you closely for at least 12 weeks after stopping BKEMV for signs of worsening aHUS symptoms or problems related to abnormal clotting (thrombotic microangiopathy).**

  Symptoms or problems that can happen with abnormal clotting may include:

  - stroke
  - difficulty breathing
  - confusion
  - kidney problems
  - seizure
  - swelling in arms or legs
  - chest pain (angina)
  - a drop in your platelet count

What are the possible side effects of BKEMV?

BKEMV can cause serious side effects including:

- See **"What is the most important information I should know about BKEMV?"**
- **Serious infusion-related reactions.** Serious infusion-related reactions can happen during your BKEMV infusion. Tell your healthcare provider or nurse right away if you get any of these symptoms during your BKEMV infusion:
  - chest pain
  - trouble breathing or shortness of breath
  - swelling of your face, tongue, or throat
  - feel faint or pass out

If you have an infusion-related reaction to BKEMV, your healthcare provider may need to infuse BKEMV more slowly or stop BKEMV. See **"How should I receive BKEMV?"**

The most common side effects in people with PNH treated with BKEMV include:

- headache
- pain or swelling of your nose or throat (nasopharyngitis)
- back pain
- nausea

The most common side effects in people with aHUS treated with BKEMV include:

- headache
- diarrhea
- high blood pressure (hypertension)
- common cold (upper respiratory infection)
- stomach-area (abdominal pain)
- vomiting
- pain or swelling of your nose or throat (nasopharyngitis)
- low red blood cell count (anemia)
- cough
- swelling of legs or feet (peripheral edema)
- nausea
- urinary tract infections
- fever

The most common side effects in people with gMG treated with BKEMV include:

- muscle and joint (musculoskeletal) pain

The most common side effects in people with NMOSD treated with BKEMV include:

- common cold (upper respiratory infection)
- pain or swelling of your nose or throat (nasopharyngitis)
- diarrhea
- back pain
- dizziness
- flu like symptoms (influenza) including fever, headache, tiredness, cough, sore throat, and body aches
- joint pain (arthralgia)
- throat irritation (pharyngitis)
- bruising (contusion)

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of BKEMV.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of BKEMV.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about BKEMV that is written for health professionals.

What are the ingredients in BKEMV?

Active ingredient: eculizumab-aeeb

Inactive ingredients: sorbitol (E420), acetic acid, polysorbate 80 (vegetable origin), edetate disodium (EDTA), sodium hydroxide may be added to adjust pH, and Water for Injection, USP.

AMGEN

BKEMV® (eculizumab-aeeb)

Manufactured by:
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Thousand Oaks, CA 91320-1799 U.S.A.

U.S. License Number 1080

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This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised 06/2026