

WHAT TO EXPECT



BKEMV is given to you by a healthcare professional through an intravenous (IV) infusion.



Before treatment with BKEMV, you must complete or update your meningococcal vaccine(s) at least 2 weeks before your first dose of BKEMV.*



Adults will usually receive a BKEMV infusion every week for the first 5 weeks then every two weeks thereafter. For children younger than 18 years of age with aHUS, the healthcare provider will decide at what dosing and how often they will receive BKEMV, based on their body weight.



Each infusion will last about 35 minutes for adults and 1 to 4 hours for children. After each infusion, you should be monitored by a healthcare provider for at least 1 hour.

aHUS, Atypical Hemolytic Uremic Syndrome

*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.

APPROVED USE

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.

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

Please see additional Important Safety Information, including BOXED Warning, on pages 4-5.

INFUSION TRACKER



The following pages are meant to be filled out after each infusion takes place so that you can track how you are feeling. You can also note any side effects that you may be experiencing or questions that you have for your healthcare team.

Infusion# _____

Date: _____ Time: _____

How are you feeling after completing your infusion?

What are some items you'd like to remember to bring for your next infusion?

Have you experienced any side effects after your infusion?

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

Do you have any questions for your doctor or healthcare team for your next visit?

IMPORTANT SAFETY INFORMATION

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

BKEMV is a medicine that affects your immune system and 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 that 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 been vaccinated and BKEMV must be started right away, you should receive the required vaccine(s) as soon as possible.

Please see additional Important Safety Information, including BOXED Warning, on pages 4-5.

BEFORE INFUSION CONSIDERATIONS

Here's a list of considerations to keep in mind before your infusion. Once you've completed the corresponding task, add a check mark (✓) in the box below.

		✓
	Confirm the date, time, and address of your infusion	<input type="checkbox"/>
	Inform your healthcare provider if you think you have an infection or fever, are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed	<input type="checkbox"/>
	Inform your healthcare provider about all the medicines you take and any recent vaccinations or if you are scheduled to receive any vaccinations. You should receive any required meningococcal vaccinations at least 2 weeks before you start treatment with BKEMV (eculizumab-aeeb)	<input type="checkbox"/>
	Arrange for transportation or ask your doctor if you can drive yourself	<input type="checkbox"/>
	Ask your doctor if you should eat, drink, or take any medications before arriving	<input type="checkbox"/>
	Wear warm, comfortable clothes with sleeves that are easy to roll up	<input type="checkbox"/>
	Bring some things to help pass the time (like books, a tablet, or music)	<input type="checkbox"/>
	Check in with your Patient Access Liaison (PAL).*	<input type="checkbox"/>

* If you have a BKEMV prescription and haven't connected with a Patient Access Liaison (PAL), you can call 1-866-402-5622 Monday-Friday, 8 AM-5 PM CST. The PAL is a dedicated support partner who helps investigate, explain, and educate on the steps in your treatment experience. Your PAL partner may support and champion you while accomplishing your treatment goals.

Your healthcare provider will give you a REMS Patient Safety Card detailing the risk of serious meningococcal infection. You will need to carry your REMS Patient Safety Card with you at all times while you are receiving BKEMV treatment and for 3 months after your last dose.

Please see additional Important Safety Information, including BOXED Warning, on pages 4-5.

IMPORTANT SAFETY INFORMATION (CONT'D)

- If you have not been vaccinated and BKEMV must be started right away, you should also receive antibiotics 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 rash, headache with nausea or vomiting, headache with a stiff neck or stiff back, or 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 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.

BKEMV may also increase the risk of other types of serious infections, 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 occur if you take BKEMV and have a weak immune system or a low white blood cell count.

Who should not receive BKEMV?

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

IMPORTANT SAFETY INFORMATION (CONT'D)

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, and are breastfeeding or plan to breastfeed. It is not known if BKEMV will harm your unborn baby or if it passes into your breast milk.

Tell your healthcare provider about all the vaccines you receive and medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements which could affect your treatment. 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.

What are the possible side effects of BKEMV?

BKEMV can cause serious side effects, including serious infusion-related reactions. Tell your healthcare provider or nurse right away if you get any of these symptoms during your BKEMV infusion: headache, back pain, diarrhea, upper respiratory infection, urinary tract infections, fever, pain in your abdomen, pain or swelling of your nose or throat, common cold, cough, nausea, vomiting, chest pain, high blood pressure, low red blood cell count, trouble breathing or shortness of breath, swelling of your face, tongue, or throat, swelling of legs or feet, muscle and joint pain, and feeling faint or passing out. If you have an infusion-related reaction to BKEMV, your healthcare provider may need to infuse BKEMV more slowly, or stop BKEMV.

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. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at [1-800-FDA-1088](tel:1-800-FDA-1088).

Please see full Prescribing Information and Medication Guide for BKEMV.