

BEKEMV[®] ▼ (eculizumab) PATIENT CARD

▼ This medicinal product 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. Side effects can also be reported to Amgen Limited on +44 (0) 1223 436441.

This card is an additional risk minimization measure and fulfils the conditions of the marketing authorization. It has been approved by the MHRA.

 **Important Safety Information for Patients Receiving BEKEMV**
Show this card to any doctor involved in your care.

Meningococcal vaccination is required prior to the start of treatment with BEKEMV. Revaccination is required in accordance with current national vaccination guidelines for vaccination use.

BEKEMV can lower the ability of your immune system to fight infections. Serious infections including sepsis may develop, **especially meningococcal infection, which requires immediate medical attention**. If you experience any of the following symptoms, you should **immediately call your doctor**.

If you cannot reach your doctor, go to an Accident and Emergency department and show them this card.

- Headache with nausea or vomiting
- Headache with a stiff neck or stiff back
- Fever (raised temperature)
- Rash
- Confusion
- Muscle aches with flu-like symptoms
- Eyes sensitive to light



Seek emergency medical care immediately if you have any of these signs or symptoms and show this card.

Even if you stop using BEKEMV, keep this card with you for 3 months after your last BEKEMV dose. Your risk of meningococcal infection may continue for a long time after your last dose of eculizumab.

This medicine contains sorbitol. Sorbitol is a source of fructose. If you (or your child) have hereditary fructose intolerance (HFI), a rare genetic disorder, you (or your child) must not receive this medicine. People with HFI cannot break down fructose, which may cause serious side effects, like seizures, coma, growth delay (in children), kidney and liver failure.

PATIENT CARD

Information for the Treating Doctor

This patient has been prescribed **BEKEMV (eculizumab)**, which increases the patient's susceptibility to meningococcal infection (*Neisseria meningitidis*) or other general infections.

- Meningococcal infections may become rapidly life-threatening or fatal if not recognised and treated early.
- **Evaluate immediately if infection is suspected and treat with appropriate antibiotics if necessary.**
- Contact prescribing doctor (below) as soon as possible.
- All patients must be vaccinated at least 2 weeks prior to receiving eculizumab. Patients who initiate eculizumab less than 2 weeks after receiving meningococcal vaccine must receive appropriate prophylactic antibiotics until 2 weeks after vaccination.
- Patients must receive vaccination and revaccination according to current national vaccination guidelines for vaccination use.

- BEKEMV is contraindicated in patients with HFI regardless of their age, and in all babies and children under 2 years of age who may not yet be diagnosed with HFI.
- After intravenous administration of a sorbitol containing medicine like BEKEMV, patients with HFI may present with hypoglycemia, metabolic acidosis, seizures and/or coma. These conditions can be life threatening. Evaluate immediately if HFI is suspected and treat appropriately.
- For more information about BEKEMV, please refer to the full Summary of Product Characteristics
<https://www.medicines.org.uk/emc/product/15378/smpc> or email gbinfoline@amgen.com or telephone 01223 436441.

▼ This medicinal product is subject to additional monitoring. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Amgen Limited on +44 (0) 1223 436441.

 Patients receiving eculizumab should carry this card at all times. Show this card to any doctor involved in your healthcare.

Patient name

Hospital where treated

Doctor's name

Doctor's Telephone number

Meningococcal Vaccination date(s)

Meningococcal re-vaccination date