

BEKEMV®▼(eculizumab)

Guide for Healthcare Professionals

The aim of this guide is to help reduce the risk of meningococcal infection associated with the use of BEKEMV and to increase awareness of the need for vaccination

This guide is an additional risk minimisation measure and fulfils the conditions of the marketing authorisation. It has been approved by the HPRA.

**This guide should be used in conjunction with the Summary of Product Characteristics (SmPC) for BEKEMV.
www.medicines.ie**

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects via the instructions given in section “Reporting Adverse Drug Reactions”



CONTENTS

PAGE

SUMMARY OF IMPORTANT RISKS AND RECOMMENDED PROCEDURES FOR THEIR PREVENTION AND/OR MINIMISATION	3
IMPORTANT SAFETY INFORMATION	4
Before starting treatment with eculizumab	4
During treatment with eculizumab	4
Other systemic infection	4
Sorbitol content warning	5
INFORMATION TO PROVIDE TO PATIENTS	5
REFERENCES	6
REPORTING ADVERSE DRUG REACTIONS	6
MORE INFORMATION	6

SUMMARY OF IMPORTANT RISKS AND RECOMMENDED PROCEDURES FOR THEIR PREVENTION AND/OR MINIMISATION

Use of eculizumab:

- increases the risk of meningococcal infection (*Neisseria meningitidis*)
 - All patients should be monitored for signs and symptoms of meningitis during treatment.
 - Sepsis is a common presentation of meningococcal infection.
 - Vaccinate patients against *Neisseria meningitidis* at least 2 weeks prior to receiving eculizumab and/or provide antibiotic prophylaxis.
 - Repeat vaccination according to current national guidelines.
- increases the risk of other systemic infections
 - Patients under 18 years of age must be vaccinated against *Haemophilus influenzae* and pneumococcus.

Patients/parents/caregivers should be provided with the following materials for BEKEMV, and ensure they understand the content:

- Patient Card
- Guide for Patients/Parents/Caregivers
- Package Leaflet

BEKEMV is contraindicated in patients with Hereditary Fructose Intolerance (HFI) regardless of their age, and in babies and children under 2 years of age who may not yet be diagnosed with HFI. BEKEMV therapy must not be initiated in patients:

- with unresolved *Neisseria meningitidis* infection
- who are not currently vaccinated against *Neisseria meningitidis* unless they receive prophylactic treatment with appropriate antibiotics until 2 weeks after vaccination.

IMPORTANT SAFETY INFORMATION¹

Serious meningococcal infections

Due to its mechanism of action, the use of **eculizumab increases the risk of severe infection and sepsis, especially meningococcal infection (*Neisseria meningitidis*)** for the patient.

Cases of serious or fatal meningococcal infections have been reported in eculizumab-treated patients.

Sepsis is a common presentation of meningococcal infections in patients treated with eculizumab.

The following steps must be taken to minimise the risk of infection and the risk of poor outcomes following infection:

Before starting treatment with eculizumab:

- Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving eculizumab unless the risk of delaying eculizumab therapy outweighs the risks of developing a meningococcal infection.
 - Patients who start treatment with eculizumab less than 2 weeks after receiving vaccination should be treated with antibiotic prophylaxis until 2 weeks after vaccination.
- Vaccinate according to current national vaccination guidelines.
- Vaccination may not be sufficient to prevent meningococcal infection. Consideration should be given to official guidance on the appropriate use of antibacterial agents.
- Vaccination (or revaccination) may further activate complement. As a result, patients with complement-mediated diseases may experience increased signs and symptoms of their underlying disease. Therefore, patients should be closely monitored for disease symptoms after recommended vaccination.

During treatment with eculizumab:

- All patients should be monitored for early signs of meningococcal infection, evaluated immediately if infection is suspected, and treated with appropriate antibiotics if necessary.
- Revaccinate patients according to current national guidelines for vaccination of patients treated with complement inhibitors.

Other systemic infections

Due to its mechanism of action, eculizumab therapy should be administered with caution to patients with active systemic infections. Patients may have increased susceptibility to infections, especially with *Neisseria* and encapsulated bacteria.

Serious infections with *Neisseria* species (other than *Neisseria meningitidis*), including disseminated gonorrhoeae, have been reported. Physicians should advise patients about gonorrhoea prevention.

Patients under 18 years of age should be vaccinated against *Haemophilus influenzae* and pneumococcus. National vaccination guidelines for each age group should be followed.

Sorbitol Content Warning

Each mL of this medicinal product contains 50 mg of sorbitol (E420). Patients with hereditary fructose intolerance (HFI³) must not take this medicine. In HFI patients more than 2 years old, a spontaneous aversion for fructose-containing foods develops and may be combined with the onset of symptoms (vomiting, gastrointestinal disorders, apathy, height and weight retardation). Therefore, a detailed history with regard to HFI symptoms has to be taken of each patient prior to receiving BEKEMV. In case of inadvertent administration and suspicion of fructose intolerance the infusion has to be stopped immediately, normal glycaemia has to be re-established and organ function has to be stabilized by means of intensive care.

Babies and children (below 2 years of age) may not yet be diagnosed with HFI. Medicines containing sorbitol/fructose given intravenously may be life-threatening and must be contraindicated in this population.

INFORMATION TO PROVIDE TO PATIENTS

You'll be provided with the following materials that need to be given to each patient being treated with BEKEMV.

- **Patient Card:** Informs patients and healthcare professionals about the risk of meningococcal infections associated with eculizumab. This should be carried at all times and for 3 months after the last dose. It should be shown to healthcare professionals they see.
- **Guide for patient/parent/caregiver:** Educates on the risk of meningococcal infections and the need for vaccination.
- **Package Leaflet**

Please read and explain these materials to patients.

Inform patients and parents/caregivers about the risk of meningococcal infection. Educate on the following key messages:

- If patients suspect infection, seek immediate medical attention.
- Relevant signs and symptoms² include:
 - Headache with nausea or vomiting
 - Headache with a stiff neck or back
 - Fever
 - Rash
 - Confusion
 - Severe muscle ache combined with flu-like symptoms
 - Sensitivity to light

In children, additional signs and symptoms to those listed above may include:

- Rapid breathing
- Cold hands and feet
- Refusing food and/or vomiting
- Unusual crying or moaning
- Stiff neck
- Being drowsy or difficult to wake
- Irritability
- Convulsions/seizures

Ensure that the parents/caregivers/guardians can confidently identify typical symptoms of headache, fever, and neck stiffness which may be hard to detect in younger children, so train them to be aware of other symptoms including inactivity, irritability, vomiting, and poor feeding and to seek urgent medical attention.

Inform patients/parents/caregivers on the vaccination requirements regarding:

- Vaccinations and/or antibiotic prophylaxis before starting treatment with eculizumab
- Revaccination in line with national guidelines

Inform patients/parents/caregivers on the risks of serious metabolic harm to patients with HFI if they are exposed to intravenous sorbitol (sorbitol is included in BEKEMV's formulation).

REFERENCES

1. BEKEMV <https://www.medicines.ie/> Summary of Product Characteristics. Amgen Technology (Ireland) UC.
2. Meningitis: <https://www2.hse.ie/conditions/meningitis-septicaemia-children-babies> and <https://www.gov.uk/government/publications/meningococcal-disease-guidance-on-public-health-management>
3. Hereditary Fructose Intolerance: <https://www.ncbi.nlm.nih.gov/books/NBK333439/> [Accessed September 2025]

REPORTING ADVERSE DRUG REACTIONS

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

Please report any suspected adverse reactions to the HPRA using the available methods via www.hpra.ie.

Reports can also be made to Amgen directly by contacting Amgen Ireland on +44 (0) 1223 436441 or Freephone 1800 535 160.

Please report any potential quality complaint with an Amgen product by calling us on +44 (0) 1223 436441 or Freephone 1800 535 160 and providing us with the details. Please ensure that you keep the packaging, so we are able to identify the product more easily.

MORE INFORMATION

Should you have any questions or require additional information regarding the use of BEKEMV, please contact on +44 (0) 1223 436441, Freephone 1800 535 160 or by email at gbinfoline@amgen.com.