

# BEKEMV®▼(eculizumab) Vaccination/Prophylaxis antibiotic Certificate

To: Amgen _____	Date: _____
Fax: _____	
Email: _____	

Ecuzumab is authorized under controlled distribution for use in the treatment of adults and children with paroxysmal nocturnal haemoglobinuria (PNH) and Atypical haemolytic uremic syndrome (aHUS). Distribution of the medicinal product is only possible after your written confirmation at the 1<sup>st</sup> order that you as the hospital understand that the patient received or will receive meningococcal vaccination and/or antibiotic prophylaxis. It is also required that all healthcare professionals ensure that they have read and understood the Physician's Guide before prescribing ecuzumab for any patient. The physician should also discuss the Patient's/Parent's Information Brochure with the patient/parent(s)/legal guardian(s) during consultation and provide it to the patient or parent(s)/legal guardian(s) along with the Patient Safety Card.

**Please send with 1<sup>st</sup> order by fax or email**

Name of Hospital/Clinic:	Phone:
Address:	Fax:
City, Postal code, Country:	Email:

## Vaccination / antibiotic prophylaxis

- ☐ The patient has been vaccinated against meningococcus  
 (Recommendation: vaccines against serogroups A, C, Y, W 135 and B or as per regional regulations)
- ☐ at least 2 weeks before receiving the first dose of the ecuzumab.
  - ☐ less than 2 weeks before receiving the first dose of ecuzumab and therefore will receive appropriate antibiotic prophylaxis at the latest from the 1st day of treatment with ecuzumab until 2 weeks after vaccination against meningococcal disease.
- ☐ will receive antibiotic prophylaxis from day 1 of treatment and throughout the duration of treatment (as vaccination against meningococcal disease is contraindicated or not possible at the time).

Date of Vaccination \_\_\_\_\_ Date of initiation of antibiotic therapy \_\_\_\_\_

## Commitment

- ☐ I, the undersigned, \_\_\_\_\_ hereby undertake to ensure and confirm that: I must explain ecuzumab treatment to the patient/parent(s)/legal guardian(s) and I must deliver to the patient/ parent(s)/legal guardian(s) all necessary information, including the Patient Safety Card and relevant patient educational materials before treatment initiation.
- ☐ I understand that I can request additional copies of BEKEMV (eculizumab) educational materials consisting of: Patient Safety Card, Physician's Guide, Patient's/Parent's Information Brochure via local Amgen safety contacts. Tel: +966 112 799328 E-mail: [safety-mea@amgen.com](mailto:safety-mea@amgen.com)

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## BEKEMV®▼(eculizumab) Vaccination/Prophylaxis antibiotic Certificate *(continued)*

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get to local Amgen safety contacts or the national pharmacovigilance center at Saudi FDA.

### Risk of meningococcal infection and vaccination/antibiotic prophylaxis

- ☐ Due to its mechanism of action, I understand the use of BEKEMV increases the patient's susceptibility to meningococcal infections/sepsis (*Neisseria meningitidis*). Meningococcal diseases can be caused by any serogroup.
- To reduce this risk of infection, all patients must be vaccinated against all serotypes of *Neisseria meningitidis* meningococcal infection for which vaccines are available, in accordance with national vaccination guidelines at least two weeks before receiving the first dose of BEKEMV.
  - If a patient starts BEKEMV treatment less than 2 weeks after meningococcal vaccination, they must be treated with appropriate antibiotic prophylaxis from the first day of treatment with BEKEMV until 2 weeks after being vaccinated against meningococcal infection.

### Sorbitol Warning

- ☐ I understand that eculizumab contains sorbitol and is therefore 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 as after intravenous administration of a sorbitol- containing medicine like eculizumab, patients with HFI may present severe metabolic abnormalities and life-threatening symptoms including hypoglycemia, metabolic acidosis, seizures, coma

### Privacy Statement

- ☐ I confirm that I have read and understood all statements and I will ensure that I do not treat patients who are contraindicated, and that all patients I treat with BEKEMV will have adequate meningococcal protection in accordance with the above requirements.

**Date:** (MM-DD-YYYY)

**Signature:**

This document is approved by the Executive Directorate of Pharmacovigilance at SFDA  
Should you have any questions or require additional information regarding the use of BEKEMV, you can refer to the patient information leaflet