BEKEMV®▼(eculizumab) Vaccination/Prophylaxis antibiotic Certificate

To: Amgen _____ Date: _____

Fax: _____

Email: _____

Eculizumab is authorized under controlled distribution for use in the treatment of adults and children with paroxysmal nocturnal haemoglobinuria (PNH). Distribution of the medicinal product is only possible after your written confirmation at the 1st 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 eculizumab 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 1st 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 eculizumab.

☐ less than 2 weeks before receiving the first dose of eculizumab and therefore will receive appropriate antibiotic prophylaxis at the latest from the 1st day of treatment with eculizumab 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 eculizumab 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

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AMGEN®

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.

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

☐ For the purposes of supplying BEKEMV (eculizumab), Amgen will process any personal data, details of the processing and protection of personal data, as well as the Privacy Statement will be ensured as per the local privacy regulations.

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