

## EPYSQLI™ Certificate of Prescriber Enrollment (Saudi Arabia)

Healthcare professionals may only prescribe EPYSQLI™▼ (eculizumab) under the controlled distribution system (CDS). Under the EPYSQLI CDS, EPYSQLI that is prescribed to a patient will only be distributed once Samsung Bioepis receives this completed Certificate form as written confirmation that you as a prescriber have understood that every patient has received or will receive meningococcal vaccination and/or antibiotic prophylaxis in accordance with the *Meningococcal Vaccination Requirements* set out in this Certificate form.

Please send this completed Certificate to Samsung Bioepis at [XXXX@XXXX.com](mailto:XXXX@XXXX.com).

PRESCRIBER INFORMATION	
First name*	
Surname*	
Email address*	
Phone number*	
TREATING HOSPITAL INFORMATION	
Name*	
Hospital Address*	Postal code:

\*required

**By completing, signing and submitting this Certificate, I acknowledge and agree that:**

- I have read and understood:
  - the *EPYSQLI Prescribing Information (PI)*, *Physician's Guide*, *Patient/Parent/Legal Guardian Guide*, the *Patient Card* and the *Privacy Notice*; and
  - the *Meningococcal Vaccination Requirements* set out in this Certificate.
- Before commencing EPYSQLI treatment for the patient:
  - I have explained the treatment to the patient or their parent(s)/legal guardian(s) and provided them with information about the treatment, including *Patient/Parent/Legal Guardian Guide*, *the Patient Card* and any other relevant educational materials; and
  - I have minimised the patient's risk of developing meningococcal infection in accordance with the *Meningococcal Vaccination Requirements* set out in this Certificate, and any applicable national guidelines.
- To the extent I have received additional relevant educational materials from Samsung Bioepis, I shall provide these materials to the patient as well.
- I confirm my consent for processing and transferring my personal data to Samsung Bioepis including the transfer of my personal data outside the Kingdom of Saudi Arabia along with this Certificate.
- I will receive an annual vaccination reminder to check each patient's vaccination status.

### Meningococcal Vaccination Requirements

Due to its mechanism of action, the use of EPYSQLI increases the patient's susceptibility to meningococcal infection (*Neisseria meningitidis*). Meningococcal disease due to any

serogroup may occur. To reduce the risk of meningococcal infection and the risk of poor outcomes following infection, the following steps must be taken.

- All patients must be vaccinated with a meningococcal vaccine at least 2 weeks prior to receiving EPYSQLI unless the risk of delaying EPYSQLI therapy outweighs the risk of developing a meningococcal infection.
- Patients who initiate EPYSQLI treatment less than 2 weeks after receiving a tetravalent meningococcal vaccine must receive treatment prophylactic antibiotics until 2 weeks after vaccination.
- Vaccines against serogroups A, C, Y, W 135 and B, where available, are recommended in preventing the commonly pathogenic meningococcal serogroups.
- Patients must receive vaccination or revaccination according to current national vaccination guidelines for vaccination use. If switching from a different complement inhibitor treatment (including other eculizumab products) to EPYSQLI, physicians should confirm that the patient’s meningococcal vaccination is current according to applicable national guidelines.
- Vaccination may not be sufficient to prevent meningococcal infection. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

<b>Prescriber Signature</b>	
Prescriber Signature:	Date (DD/MM/YYYY):
<b>Samsung Bioepis’ Data Privacy Notice</b>	
<p>Samsung Bioepis Co., Ltd., and its local affiliates (collectively, “Samsung Bioepis”, “we”, “us”) are controllers of healthcare professional personal data. These are healthcare professionals involved in the therapeutic management of eculizumab.</p> <p>The purpose of this processing is to manage and mitigate the risks associated with the use of eculizumab, as required by law.</p> <p>The healthcare professional’s personal data we process includes prescriber’s name, hospital affiliation when providing the completed prescriber enrollment form (PEF) or when identified as treating physicians, and email address when submitting the prescriber enrollment form either electronically or in paper.</p> <p>To fulfil a prescription order we will share this data with our third party distributors.</p> <p>You may contact us at any time to:</p> <ul style="list-style-type: none"> <li>• ask what personal data we process about you and request a copy;</li> <li>• ask us to rectify any inaccurate personal data;</li> <li>• suppress or opt out of certain processing activities;</li> <li>• delete your personal data, or impose restrictions on our processing of your personal data;</li> <li>• object to the processing of your personal data by us on specific grounds;</li> <li>• withdraw your consent to certain processing activities involving your personal data;</li> </ul>	

- exercise any other data privacy rights available to you under applicable law

If complying with such a request means that Samsung Bioepis or its affiliates would be in breach of their obligations under applicable laws, regulations or codes of practice, then Samsung Bioepis may be unable to comply with your request.

To exercise the above rights, please contact: [sbe.privacy@samsung.com](mailto:sbe.privacy@samsung.com)

To learn more about how we collect and process your personal data, including how long we retain your data for, please visit our website: [<DPN website link TBD>](#) or use the QR Code below. This includes details of our full data privacy notice.

Placeholder for  
QR code

**FOR SAMSUNG BIOEPIS USE ONLY**

**Unique Prescriber ID:** \_\_\_\_\_

Once the Unique Prescriber ID is allocated by Samsung Bioepis, it **must** be provided for any further orders of EPYSQLI™.

**To report any side effect(s), please contact:**

The National Pharmacovigilance Centre (NPC) - Saudi Food and Drug Authority (SFDA):

SFDA Call Center: 19999

E-mail: [npc.drug@sFDA.gov.sa](mailto:npc.drug@sFDA.gov.sa)

Website: <https://ade.sfda.gov.sa>



Or

PharmaKnowl Consulting

Email: [gppv-saudi@pharmaknowl.com](mailto:gppv-saudi@pharmaknowl.com)

Phone: +966112777729 / +966112404409