



EPYSQLI REMS

Healthcare Provider Safety Brochure

**This brochure provides information
for healthcare providers who will prescribe
or dispense EPYSQLI**

It describes:

- What is EPYSQLI?
 - What is the EPYSQLI REMS?
 - Prescriber Requirements
 - Healthcare Setting and Pharmacy Requirements
 - EPYSQLI REMS Resources
 - Adverse Event Reporting
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What is EPYSQLI?

EPYSQLI is indicated for the treatment of:

- Patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
- Patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
- Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Limitation of Use

- EPYSQLI is not indicated for the treatment of patients with Shiga toxin *E.coli* related hemolytic uremic syndrome (STEC-HUS).

Risk of Serious Meningococcal Infections

- EPYSQLI, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains.
- Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors such as EPYSQLI.
- The initiation of EPYSQLI is contraindicated in patients with unresolved serious *Neisseria meningitidis* infection.
- Complete or update meningococcal vaccination (for serogroups A, C, W, Y, and B) at least 2 weeks prior to administering the first dose of EPYSQLI, according to current Advisory Committee on Immunization Practices (ACIP) recommendations for patients receiving a complement inhibitor.
- If urgent EPYSQLI therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible.
- Vaccination does not eliminate the risk of serious meningococcal infections, despite development of antibodies following vaccination.
- Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Promptly treat known infections.
- Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if these signs and symptoms occur.

- Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.
- Consider interruption of EPYSQLI in patients who are undergoing treatment for serious meningococcal infection, depending on the risks of interrupting treatment in the disease being treated.

What is the EPYSQLI REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a program required by the Food and Drug Administration (FDA) to help ensure that the benefits of a drug outweigh its risks.

Because of the risk of serious meningococcal infections, EPYSQLI is available only through the EPYSQLI REMS, a restricted distribution program.

Prescriber Requirements

What do Prescribers Need to do When Prescribing EPYSQLI?

Healthcare providers who prescribe EPYSQLI must be specially certified. To become certified in the EPYSQLI REMS and prescribe EPYSQLI, prescribers must:

- Review the EPYSQLI Prescribing Information.
- Review the **Healthcare Provider Safety Brochure** (this document).
- Review the **Patient Safety Card**.
- Review the **Patient Guide**.
- Complete and submit the **Prescriber Enrollment Form** to the EPYSQLI REMS.
 - online at www.EPYSQLIREMS.com
 - By fax at 1-866-318-8144

Prescribers will be notified within 2 business days when their certification in the EPYSQLI REMS is complete and they can prescribe EPYSQLI.

Before initiating a patient's EPYSQLI treatment, prescribers must:

- Assess the patient for unresolved meningococcal infection and not initiate EPYSQLI in any patient with these infections.

- Assess the patient's vaccination status for meningococcal serogroups A, C, W, Y, and B and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
- For patients who are not up to date with meningococcal vaccines at least two weeks prior to initiation of treatment and who must start EPYSQLI urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
- Counsel the patient using the **Patient Safety Card** and **Patient Guide**. Provide a copy of the materials to the patient.
 - The **Patient Guide** provides information for your patients about the risk of serious meningococcal infections including:

- The need to complete or update their meningococcal vaccines for serotypes A, C, W, Y, and B at least two weeks prior to receiving the first dose of EPYSQLI or receive antibacterial drug prophylaxis if EPYSQLI must be initiated immediately, and they have not previously been vaccinated.
- Additional vaccines may be necessary during treatment with EPYSQLI.
- Meningococcal vaccines do not prevent all meningococcal infections.

- The **Patient Safety Card** has important safety information for both patients and any healthcare providers that may see or treat your patient. It describes the following signs and symptoms which, if experienced, should prompt the patient to seek immediate medical evaluation:

- fever
- fever and a rash
- fever with high heart rate
- headache with nausea or vomiting
- headache and fever
- headache with stiff neck or stiff back
- confusion
- eyes sensitive to light
- muscle aches with flu-like symptoms

- Counsel the patient on the need to carry the **Patient Safety Card**. Instruct your patient to show the card to any healthcare provider involved in their care.
 - Instruct the patient to carry the **Patient Safety Card** at all times and for 3 months after their last dose.

During EPYSQLI treatment, prescribers must:

- Assess the patient for early signs and symptoms of meningococcal infection and evaluate immediately if infection is suspected.
- Vaccinate patients as needed according to the ACIP recommendations for meningococcal vaccinations for patients receiving a complement inhibitor.

At all times, prescribers must:

- Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes by phone at 1-888-483-8279 (Teva Pharmaceuticals).
- Comply with the EPYSQLI REMS requirements to maintain certification to prescribe.

Before dispensing, certified healthcare settings and pharmacies must assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B according to the current ACIP recommendations including antibacterial drug prophylaxis, if needed. If you have not provided this information already, you may receive a call from the healthcare setting and pharmacy to collect information confirming that the patient has received the appropriate vaccinations or antibacterial drug prophylaxis.

Healthcare Setting and Pharmacy Requirements

What do Healthcare Settings and Pharmacies Need to do When Dispensing EPYSQLI?

EPYSQLI may only be dispensed by healthcare settings and pharmacies that are certified to dispense. To become certified, the healthcare setting and pharmacy must designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting or pharmacy. To become certified, the Authorized Representative must:

- Review the **Healthcare Provider Safety Brochure** (this document).
- Complete and submit the **Healthcare Setting and Pharmacy Enrollment Form** to the REMS:
 - online at www.EPYSQLIREMS.com
 - By fax 1-866-318-8144

By completing the Healthcare Setting and Pharmacy Enrollment Form, the Authorized Representative agrees to:

- Train all relevant staff involved in dispensing EPYSQLI using the **Healthcare Provider Safety Brochure**.
- Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B according to the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis, if needed, before treatment initiation and document the findings.

- For patients who are not up to date with meningococcal vaccines when starting treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal vaccines including antibacterial drug prophylaxis, if needed, before dispensing prescriptions up to 6 months after the first dose and document the findings.

Before dispensing the first dose, all healthcare setting and pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- Assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.

Before dispensing, up to 6 months after the first dose, the healthcare setting and pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- For patients who are not initially up to date with meningococcal vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.

Before dispensing, 6 months after the first dose and thereafter, the healthcare setting and pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.

At all times, all healthcare setting and pharmacy staff must:

- Report adverse events suggestive of meningococcal infection by phone at 1-888-483-8279 (Teva Pharmaceuticals).
- Not distribute, transfer, loan, or sell EPYSQLI, except to certified healthcare settings and certified pharmacies.
- Maintain records of staff's completion of REMS training.
- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits carried out by Samsung Bioepis Co., Ltd. or a third party acting on behalf of Samsung Bioepis Co., Ltd., to ensure that all processes and procedures are in place and are being followed.

To maintain certification to dispense, any new Authorized Representative must:

- Enroll by completing and submitting the **Healthcare Setting and Pharmacy Enrollment Form** to the REMS.

EPYSQLI REMS Resources

Visit www.EPYSQLIREMS.com or call 1-866-318-0342 to learn more about the EPYSQLI REMS.

Adverse Event Reporting

Report adverse events suggestive of meningococcal infections including the patient's clinical outcomes, immediately by phone at 1-888-483-8279 (Teva Pharmaceuticals).

You are encouraged to report other adverse reactions of EPYSQLI by phone at 1-888-483-8279 (Teva Pharmaceuticals) or to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

This brochure does not provide all risk information for EPYSQLI. Please see Prescribing Information for EPYSQLI, including BOXED WARNING regarding serious meningococcal infections for more detailed safety information.





Epysqli®

(eculizumab-aagh)
Injection

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Teva Pharmaceuticals distributes EPYSQLI and maintains the EPYSQLI REMS in the US
for and in accordance with Samsung Bioepis Co., Ltd.

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