Epysqli®
(eculizumab-aagh)
Injection • 300mg/30mL

DOSING & ADMINISTRATION GUIDE FOR EPYSQLI®

An FDA-approved biosimilar interchangeable with Soliris®[1-3]

INDICATIONS

- EPYSQLI is indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
- EPYSQLI is indicated for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

  Limitation of Use

  EPYSQLI is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- EPYSQLI is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AchR) antibody positive.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Eculizumab products, complement inhibitors, increase the risk of serious infections caused by *Neisseria meningitidis*. Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of EPYSQLI, unless the risks of delaying therapy with EPYSQLI outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal bacteria in patients receiving a complement inhibitor. Initiate prophylactic antibacterial drug therapy. Vaccinate as soon as possible.**
- **Patients receiving eculizumab products are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected.**

Because of the risk of serious meningococcal infections, EPYSQLI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called EPYSQLI REMS.

Please click here for full Prescribing Information for EPYSQLI, including BOXED WARNINGS.

teva Biosimilars

EPYSQLI® has the same recommended dosing as Soliris®[4,5]

Indication

EPYSQLI is indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.

Recommended dosage

For patients 18 years of age and older, EPYSQLI therapy consists of:

Administer EPYSQLI at the recommended dosage regimen time points, or within 2 days of these time points.

View preparation, administration, and storage and handling information for EPYSQLI.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

EPYSQLI is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

Eculizumab products, complement inhibitors, increase 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.

Complete or update meningococcal vaccination (for serogroups A, C, W, Y, and B) at least 2 weeks prior to administration of the first dose of EPYSQLI, according to current ACIP recommendations for patients receiving a complement inhibitor. Revaccinate patients in accordance with ACIP recommendations, considering the duration of therapy with EPYSQLI. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information. 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. Various durations and regimens of antibacterial drug prophylaxis have been considered, but the optimal durations and drug regimens for prophylaxis and their efficacy have not been studied in unvaccinated or vaccinated patients receiving complement inhibitors, including eculizumab products. The benefits and risks of treatment with EPYSQLI, as well as the benefits and risks of antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by *Neisseria meningitidis*.

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Indication

EPYSQLI is indicated for the treatment of patients with atypical uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

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

Recommended dosage

For patients 18 years of age and older, EPYSQLI therapy consists of:

Administer EPYSQLI at the recommended dosage regimen time points, or within 2 days of these time points.

Supplemental dosing of EPYSQLI is required for adult patients with aHUS in the setting of concomitant plasmapheresis or plasma exchange, or fresh frozen plasma infusion.
See dose adjustment details.

View preparation, administration, and storage and handling information for EPYSQLI.

IMPORTANT SAFETY INFORMATION (cont'd)

Serious Meningococcal Infections (cont'd)

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. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if these signs and symptoms occur. Promptly treat known infections. 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.

EPYSQLI REMS

EPYSQLI is available only through a restricted program under a REMS called EPYSQLI REMS, because of the risk of serious meningococcal infections.

Notable requirements of the EPYSQLI REMS include the following:

- Prescribers must enroll in the REMS.
- Prescribers must counsel patients about the risk of serious meningococcal infection.

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

Recommended dosage

For patients less than 18 years of age, administer EPYSQLI based on body weight according to the table below:

Patient body weight	Induction	Maintenance	
≥40 kg	900 mg weekly for the first 4 weeks	1200 mg at week 5	1200 mg every 2 weeks thereafter
30 kg to <40 kg	600 mg weekly for the first 2 weeks	900 mg at week 3	900 mg every 2 weeks thereafter
20 kg to <30 kg	600 mg weekly for the first 2 weeks	600 mg at week 3	600 mg every 2 weeks thereafter
10 kg to <20 kg	600 mg at week 1	300 mg at week 2	300 mg every 2 weeks thereafter
5 kg to <10 kg	300 mg at week 1	300 mg at week 2	300 mg every 2 weeks thereafter

Administer EPYSQLI at the recommended dosage regimen time points, or within 2 days of these time points.

Supplemental dosing of EPYSQLI is required for pediatric patients with aHUS in the setting of concomitant plasmapheresis or plasma exchange, or fresh frozen plasma infusion.
See dose adjustment details.

View preparation, administration, and storage and handling information for EPYSQLI.

IMPORTANT SAFETY INFORMATION (cont'd)

EPYSQLI REMS (cont'd)

- Prescribers must provide the patients with the REMS educational materials.

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Indication

EPYSQLI is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AchR) antibody positive.

Recommended dosage

For patients 18 years of age and older, EPYSQLI therapy consists of:

Administer EPYSQLI at the recommended dosage regimen time points, or within 2 days of these time points.

Supplemental dosing of EPYSQLI is required for adult patients with gMG in the setting of concomitant plasmapheresis or plasma exchange, or fresh frozen plasma infusion.
See dose adjustment details.

View preparation, administration, and storage and handling information for EPYSQLI.

IMPORTANT SAFETY INFORMATION (cont'd)

EPYSQLI REMS (cont'd)

- Prescribers must assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y and B) and vaccinate if needed according to current ACIP recommendations two weeks prior to the first dose of EPYSQLI.
- Prescribers must provide a prescription for antibacterial drug prophylaxis if treatment must be started urgently and the patient is not up to date with meningococcal vaccines according to current ACIP recommendations at least two weeks prior to the first dose of EPYSQLI.
- Healthcare settings and pharmacies that dispense EPYSQLI must be certified in the REMS and must verify prescribers are certified.
- Patients must receive counseling from the prescriber about the need to receive meningococcal vaccines per ACIP recommendations, the need to take antibiotics as directed by the prescriber, and the signs and symptoms of meningococcal infection.
- Patients must be instructed to carry the Patient Safety Card with them at all times during and for 3 months following treatment with EPYSQLI.

Further information is available at www.EPYSQLIREMS.com or 1-866-318-0342.

Please click here for full Prescribing Information for EPYSQLI, including BOXED WARNINGS.

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Dose adjustments for EPYSQLI®[4]

For adult and pediatric patients with aHUS, and adult patients with gMG, supplemental dosing of EPYSQLI is required in the setting of concomitant plasmapheresis or plasma exchange (PE), or fresh frozen plasma infusion (PI).

Supplemental dose of EPYSQLI in the setting of PE/PI

Type of plasma intervention	Most recent EPYSQLI dose	Supplemental EPYSQLI dose with each plasma intervention	Timing of supplemental EPYSQLI dose
Plasmapheresis or plasma exchange	300 mg	300 mg per each plasmapheresis or plasma exchange session	Within 60 minutes after each plasmapheresis or plasma exchange
	≥600 mg	600 mg per each plasmapheresis or plasma exchange session	
Fresh frozen plasma infusion	≥300 mg	300 mg per infusion of fresh frozen plasma	60 minutes prior to each infusion of fresh frozen plasma

View preparation, administration, and storage and handling information for EPYSQLI.

IMPORTANT SAFETY INFORMATION (cont'd)

Other Infections (cont'd)

Serious infections with *Neisseria* species (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported.

Eculizumab products block terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections with *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. Additionally, *Aspergillus* infections have occurred in immunocompromised and neutropenic patients. Children treated with eculizumab products may be at increased risk of developing serious infections due to *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib). Administer vaccinations for the prevention of *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) infections according to ACIP recommendations. Patients receiving eculizumab products are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

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How to prepare EPYSQLI®[4]

Step 1

Dilute EPYSQLI to a final admixture concentration of 5 mg/mL using the following steps:

- Withdraw the required amount of EPYSQLI from the vial into a sterile syringe
- Transfer the recommended dose to an infusion bag
- Dilute EPYSQLI to a final concentration of 5 mg/mL by adding the appropriate amount (equal volume of diluent to drug volume) of 0.9% Sodium Chloride Injection, USP; 0.45% Sodium Chloride Injection, USP; or 5% Dextrose in Water Injection, USP to the infusion bag. See the chart below for the final admixed EPYSQLI 5 mg/mL infusion volume by dose and diluent volume

EPYSQLI dose	Diluent volume	Final volume
300 mg	30 mL	60 mL
600 mg	60 mL	120 mL
900 mg	90 mL	180 mL
1200 mg	120 mL	240 mL

Step 2

Gently invert the infusion bag containing the diluted EPYSQLI solution to ensure thorough mixing of the product and diluent.

Step 3

Discard any unused portion left in a vial, as the product contains no preservatives.

IMPORTANT SAFETY INFORMATION (cont'd)

Monitoring Disease Manifestations after EPYSQLI Discontinuation

Treatment Discontinuation for PNH

Monitor patients after discontinuing EPYSQLI for at least 8 weeks to detect hemolysis.

Treatment Discontinuation for aHUS

After discontinuing EPYSQLI, monitor patients with aHUS for signs and symptoms of thrombotic microangiopathy (TMA) complications for at least 12 weeks. In aHUS clinical trials, 18 patients (5 in the prospective studies) discontinued eculizumab treatment. TMA complications occurred following a missed dose in 5 patients, and eculizumab was reinitiated in 4 of these 5 patients.

Clinical signs and symptoms of TMA include changes in mental status, seizures, angina, dyspnea, or thrombosis. In addition, the following changes in laboratory parameters may identify a TMA complication: occurrence of two, or repeated measurement of any one of the following: a decrease in platelet count by 25% or more compared to baseline or the peak platelet count during EPYSQLI treatment; an increase in serum creatinine by 25% or more compared to baseline or nadir during EPYSQLI treatment; or, an increase in serum LDH by 25% or more over baseline or nadir during EPYSQLI treatment.

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How to administer EPYSQLI®[4]

Prior to administration, the admixture should be allowed to adjust to room temperature (18°C to 25°C/64°F to 77°F). The admixture must not be heated in a microwave or with any heat source other than ambient air temperature.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Only administer as an intravenous infusion.
Do not administer as an intravenous push or bolus injection.

Administer the EPYSQLI admixture by intravenous infusion over 35 minutes in adults and 1 to 4 hours in pediatric patients via gravity feed, a syringe-type pump, or an infusion pump.

Admixed solutions of EPYSQLI are stable for 24 hours refrigerated at 2°C to 8°C (36°F to 46°F) and at room temperature.

If an adverse reaction occurs during the administration of EPYSQLI, the infusion may be slowed or stopped at the discretion of the physician. If the infusion is slowed, the total infusion time should not exceed 2 hours in adults.

Monitor the patient for at least 1 hour following completion of the infusion for signs or symptoms of an infusion-related reaction.

IMPORTANT SAFETY INFORMATION (cont'd)

Monitoring Disease Manifestations after EPYSQLI Discontinuation (cont'd)

If TMA complications occur after EPYSQLI discontinuation, consider reinstitution of EPYSQLI treatment, plasma therapy [plasmapheresis, plasma exchange, or fresh frozen plasma infusion (PE/PI)], or appropriate organ-specific supportive measures.

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How to store and handle EPYSQLI®[4]

Flexible storage

Unopened vials of EPYSQLI may be stored in the original carton at controlled room temperature (not more than 86°F, or 30°C) for a single 1-month period and then returned to refrigeration for 3 days if necessary.

- Store EPYSQLI vials in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use. DO NOT FREEZE. DO NOT SHAKE
- Do not use beyond the expiration date shown on the carton

IMPORTANT SAFETY INFORMATION (cont'd)

Thrombosis Prevention and Management

The effect of withdrawal of anticoagulant therapy during eculizumab products treatment has not been established. Therefore, treatment with eculizumab products should not alter anticoagulant management.

Infusion-Related Reactions

Administration of eculizumab products may result in infusion-related reactions, including anaphylaxis or other hypersensitivity reactions. In clinical trials, no patients experienced an infusion-related reaction which required discontinuation of eculizumab. Interrupt EPYSQLI infusion and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur.

ADVERSE REACTIONS

The most frequently reported adverse reactions in the PNH randomized trial (≥10% overall and greater than placebo) are: headache, nasopharyngitis, back pain, and nausea.

The most frequently reported adverse reactions in aHUS single arm prospective trials (≥20%) are: headache, diarrhea, hypertension, upper respiratory infection, abdominal pain, vomiting, nasopharyngitis, anemia, cough, peripheral edema, nausea, urinary tract infections, pyrexia.

The most frequently reported adverse reaction in the gMG placebo-controlled clinical trial (≥10%) is: musculoskeletal pain.

DRUG INTERACTIONS

Plasmapheresis, Plasma Exchange, or Fresh Frozen Plasma Infusion

Concomitant use of eculizumab products with plasma exchange (PE), plasmapheresis (PP) or fresh frozen plasma infusion (PE/PI) treatment can reduce serum eculizumab product concentrations and requires a supplemental dose of EPYSQLI.

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- Same administration and dosing as Soliris[4,5]
- Flexible storage[4]

teva Total Support

Provides a range of support services to help your patients start and stay on therapy

Explore EPYSQLI Savings & Support

IMPORTANT SAFETY INFORMATION (cont'd)

Neonatal Fc Receptor Blockers

Concomitant use of eculizumab products with neonatal Fc receptor (FcRn) blockers may lower systemic exposures and reduce effectiveness of eculizumab products. Closely monitor for reduced effectiveness of EPYSQLI.

To report SUSPECTED ADVERSE REACTIONS, contact Teva Pharmaceuticals at 1-888-483-8279 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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References: 1. BLA approval. US Food & Drug Administration. Accessed March 25, 2025. accessdata.fda.gov/drugsatfda_docs/appletter/2024/761340Orig1s000ltr.pdf **2.** sBLA approval. US Food & Drug Administration. Accessed March 25, 2025. accessdata.fda.gov/drugsatfda_docs/appletter/2024/761340Orig1s003ltr.pdf **3.** BLA approval. US Food & Drug Administration. Accessed December 8, 2025. accessdata.fda.gov/drugsatfda_docs/appletter/2025/761340Orig2s000ltr.pdf **4.** EPYSQLI® (eculizumab-aagh) injection. Current Prescribing Information. Parsippany, NJ: Teva Pharmaceuticals. **5.** Soliris® (eculizumab) injection. Prescribing Information. Boston, MA. Alexion Pharmaceuticals, Inc.

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