

▼ **Epysqli™**  
(Eculizumab)

# Guide for Patients/Parents/ Caregivers

**This guide is intended to explain important safety information of eculizumab to patients and parents/caregivers of infants and children who are prescribed eculizumab and describes:**

- ▶ What is eculizumab?
- ▶ Important safety information about eculizumab
- ▶ Important safety information for infants and children receiving eculizumab

▼ **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. See <https://yellowcard.mhra.gov.uk/> for how to report side effects.**



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## WHAT IS ECULIZUMAB

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Epysqli (eculizumab) is used to treat adults and children with:

- Paroxysmal Nocturnal Haemoglobinuria (**PNH**)
- Atypical Haemolytic Uraemic Syndrome (**aHUS**)

Ecilizumab must be prescribed by a doctor.

You will receive the following materials from your doctor:

- **Patient Card**
  - It is very important to rapidly identify and be treated for at least 8 weeks. certain types of infection in patients who receive ecilizumab therefore, you will be given a card that lists the specific symptoms you must always look for.
  - You must carry this card at all times throughout the duration of your ecilizumab therapy and for 3 months after the last dose of ecilizumab and show it to any healthcare professional you see.
- **Guide for Patients/Parents/Caregivers**
- **Ecilizumab Patient Information leaflet**

## IMPORTANT SAFETY INFORMATION RELATED TO Eculizumab

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### Risk of Meningococcal infection

- Eculizumab may reduce your natural resistance to a certain bacteria called *Neisseria meningitidis* that may increase your risk of meningococcal infection. The meningococcal infection can lead to severe swelling of the tissues surrounding the brain and spinal cord (meningitis) and/or a severe infection of the blood (septicaemia, also known as blood poisoning or sepsis).
- These infections require urgent and appropriate care as they may become rapidly fatal or life-threatening or lead to major disabilities.
- The patient must be vaccinated and revaccinated according to current national guidelines for vaccination use.

### Before starting treatment with eculizumab:

- ▶ Your doctor will vaccinate you against meningococcal infection, at least 2 weeks before beginning therapy. If eculizumab treatment is initiated less than 2 weeks after receiving meningococcal vaccine, your doctor will make sure that you take antibiotics to reduce the risk of infection until 2 weeks after you have been vaccinated
- ▶ Vaccination reduces the risk of developing meningococcal infection, but it does not remove the risk completely. Your doctor might consider that you need additional measures to prevent infection.
- ▶ Ask your doctor if you have any questions about the vaccinations you require before starting eculizumab

### During treatment with eculizumab:

- ▶ Be aware of the signs and symptoms of meningococcal infection and notify your doctor immediately if any of these occur.

### The signs and symptoms of meningococcal infection you must look for are:

- Headache with nausea or vomiting
- Headache with a stiff neck or stiff back
- Fever
- Rash
- Confusion
- Severe muscle aches combined with flu-like symptoms
- Sensitivity to light

- ▶ You will be provided with a Patient Card. Please carry this with you at all times throughout the duration of your eculizumab therapy and for 3 months after the last dose of eculizumab and show it to any healthcare professional you see.
- ▶ If you cannot reach your doctor, go to an emergency department and show them your patient card.

The signs and symptoms of meningitis can be different in infants and children. These are described under the important safety information for infants and children who are taking eculizumab

### Risk of other infections

- Eculizumab treatment may reduce your natural resistance to other similar bacterial infections including gonorrhoea which is a sexually transmitted disease.
- Eculizumab therapy is given with caution to patients who have active infection. Before starting eculizumab, tell your doctor if you have any infections.
- If you know that you are at risk of gonorrhoea, ask your doctor or pharmacist for advice before using this medicine.
- Your doctor will administer a vaccine to your child aged less than 18 years against Haemophilus influenzae and pneumococcal infections according to the national vaccination recommendations for each age group.

### If you stop using eculizumab for aHUS

Interrupting or ending treatment with eculizumab may cause your aHUS symptoms to come back.

Your doctor will discuss the possible side effects with you and explain the risks.

Your doctor will monitor you closely.

The risks of stopping eculizumab include a problem with your platelets (an important part of the blood for clotting), which may cause:

- A large drop in the number of platelets (thrombocytopenia),
- A large increase in destruction of your red blood cells (haemolysis),
- Problems with your kidneys (decreased urination),
- Problems with your kidneys (an increase in your creatinine level),
- Confusion or change in how alert you are,
- Chest pain, (angina),
- Shortness of breath, or
- Blood clotting (thrombosis).
- If you have any of the above, contact your doctor.

## IMPORTANT SAFETY INFORMATION FOR INFANTS AND CHILDREN WHO ARE TAKING ECULIZUMAB

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Meningococcal infections are extremely dangerous and may become life-threatening within hours. Early symptoms of meningitis can include:

- Fever
- Headache
- Vomiting
- Diarrhoea
- Muscle pain
- Stomach cramps
- Fever with cold hands and feet

### Common Signs and Symptoms of Meningitis and Severe Blood Infection (Sepsis) in infants and children

- Fever
- Fretful, dislike being handled
- Rapid breathing or grunting
- Unusual cry, moaning
- Stiff neck, dislike of bright lights
- Refusing food and vomiting
- Drowsy, floppy, unresponsive
- Pale, blotchy skin spots/rash
- Tense, bulging fontanelle (soft spot on the baby's head)
- Convulsions/seizures

In children, additional signs and symptoms may include:

- Severe muscle pain
- Severe headache
- Confusion
- Irritability

Do not wait for a rash. If your child is ill and getting worse, get medical help immediately.

**Meningitis symptoms can appear in any order. Some may not appear at all. It is very important to seek medical care immediately if you see any of the above signs and symptoms.**

## REPORTING SIDE EFFECTS

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If any side effects are experienced, please talk to a doctor, pharmacist, or nurse. This includes any possible side effects not listed in the patient information leaflet or this guide.

### United Kingdom

In the UK it is easiest and quickest to report side effects online via the Yellow Card website - <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store.

## REPORTING SIDE EFFECTS TO THE MANUFACTURER

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By reporting side effects, you can help provide more information on the safety of this medicine.

You can report side effects to Samsung Bioepis, please email:

[bioepis.mi@medinformation.co.uk](mailto:bioepis.mi@medinformation.co.uk)

or call: UK: 0800 208 1063

## MORE INFORMATION

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If you require further information on eculizumab, please call or email Samsung Bioepis Medical Information.

Email: [bioepis.mi@medinformation.co.uk](mailto:bioepis.mi@medinformation.co.uk)

Tel: UK: 0800 208 1063

## HOME HEALTHCARE SERVICE

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A Home Healthcare service may be available to patients prescribed Epysqli. For more details, please ask your physician about this service

## GLOSSARY OF TERMS

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### **Anaphylactic reaction**

Extreme and severe life-threatening hypersensitivity reaction affecting the whole body, often starting with itchy rash, throat and/or tongue swelling, shortness of breath, vomiting.

### **Gonococcal infection**

Infection sexually transmitted and caused by the bacterium *Neisseria gonorrhoeae* (also named gonorrhoea). Clinical symptoms and signs can include arthritis (painful inflammation of one or more joints), arthralgias (joint pain), tenosynovitis (painful inflammation surrounding a tendon), and multiple skin lesions. Can disseminate and cause widespread blood infection (sepsis).

### **Meningococcal infection**

Infection caused by the bacterium *Neisseria meningitidis* (also named meningococcus). Can cause meningitis or widespread blood infection (sepsis).

### **Sepsis**

The presence of bacteria (bacteraemia), other infectious organisms, or toxins created by infectious organisms in the bloodstream.

## REFERENCES

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1. EPYSQLI™ (eculizumab) Current Package Leaflet. Samsung Bioepis NL, B.V.
2. NHS. Meningitis symptoms. Available from: <https://www.nhs.uk/conditions/meningitis/symptoms/> [Accessed February 2020]
3. NHS. Allergy symptoms. Available from: <https://www.nhs.uk/conditions/allergies/symptoms/> [Accessed February 2020]
4. NHS. Gonorrhoea. Available from: <https://www.nhs.uk/conditions/gonorrhoea/> [Accessed February 2020].

# SAFETY CARD



EPYSQLI ▼ (Eculizumab) SAFETY CARD

 **Important Safety Information for Patients Taking Epysqli™ ▼ (eculizumab)**

▼ '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. See <https://yellowcard.mhra.gov.uk/> for how to report side effects.' Epysqli can lower the ability of your immune system to fight

FOLD → infections, especially meningococcal infection, **which requires immediate medical attention.**

If you experience any of the following symptoms, you should immediately call your doctor or seek emergency medical care, preferably in a major emergency medical care centre:

- headache with nausea or vomiting
- headache with a stiff neck or back
- fever
- rash
- confusion
- severe muscle aches combined with flu-like symptoms
- sensitivity to light

FOLD →  **Get emergency medical care right away if you have any of these signs or symptoms and show this card.**

**Keep this card with you at all times** during treatment and for 3 months after your last Epysqli dose. Your risk of meningococcal infection may continue for several weeks after your last dose of Epysqli.

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# SAFETY CARD

## INFORMATION FOR HEALTHCARE PROFESSIONALS

- This patient has been prescribed Epysqli (eculizumab), which increases the patient's susceptibility to meningococcal infection (*Neisseria meningitidis*) or other general infections.
- All patients must be vaccinated at least 2 weeks prior to receiving Epysqli. Patients who initiate Epysqli less than 2 weeks after receiving meningococcal vaccine must receive appropriate prophylactic antibiotics until 2 weeks after vaccination.
- Patients must receive vaccination and revaccination according to current national vaccination guidelines for vaccination use.
- Meningococcal infections may become rapidly life-threatening or fatal if not recognised and treated early.
- **Evaluate immediately if infection is suspected and treat with appropriate antibiotics if necessary.**
- Contact prescribing doctor (below) as soon as possible.

Adverse events should be reported. For more information about Epysqli, please refer to the full Summary of Product Characteristics or e-mail: [bioepis.mi@medinformation.co.uk](mailto:bioepis.mi@medinformation.co.uk)

Patient name \_\_\_\_\_

Hospital where treated \_\_\_\_\_

Physician name \_\_\_\_\_

Tel. number \_\_\_\_\_

Vaccination date(s) \_\_\_\_\_

Epysqli Treatment Initiation Date: \_\_\_\_\_

Meningococcal Vaccination information:

Vaccine Brand	Vaccine Serogroup	Dose Number	Date	Primary Series/Booster Dose	Antibiotic prophylaxis received if Epysqli is initiated less than 2 weeks after receiving vaccine
					<input type="checkbox"/> Not Applicable <input type="checkbox"/> Yes, start date: _____
					<input type="checkbox"/> Not Applicable <input type="checkbox"/> Yes, start date: _____
					<input type="checkbox"/> Not Applicable <input type="checkbox"/> Yes, start date: _____

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