

**Epysqli™ ▼**  
(Eculizumab)

## Patient/Parent Information

Important safety information to minimise the risk of serious side effects

▼ 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.



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## INTRODUCTION

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This guide is for adult patients and parents/legal guardians of a child who has been prescribed eculizumab. The guide provides you with important safety information that you must be aware of.

## FREQUENTLY ASKED QUESTIONS

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### WHAT INFORMATION WILL I RECEIVE?

You will receive a starter kit containing:

- Patient Safety Card: The Patient Safety Card lists specific symptoms which you should always look out for – it is vital to be able to rapidly identify and treat certain types of infection in people who receive eculizumab. You/your child should carry this card at all times and show it to any health care professional you/your child see(s).
- Patient/Parent Information Brochure.

If you don't have any of the above documentation, you can request it from your doctor.

### WHAT STEPS SHOULD I TAKE BEFORE STARTING ECULIZUMAB?

- Ensure you/your child's vaccination status is up to date.
- Be aware of the symptoms associated with infections and what to do if you/your child experience(s) any of these symptoms.
- Ensure that you communicate with your/your child's doctor and follow his/her advice – this ensures that you/your child receives appropriate monitoring when on treatment or if the treatment is discontinued.

### I AM A PATIENT/ I AM A PARENT/LEGAL GUARDIAN OF A CHILD WHO HAS BEEN PRESCRIBED ECULIZUMAB. WHAT ADDITIONAL SAFETY PRECAUTIONS DO I NEED TO KNOW ABOUT BEFORE COMMENCING TREATMENT?

As eculizumab blocks a part of the immune system it increases the risk of severe infection and sepsis, especially by a type of bacteria called *Neisseria meningitidis*. This can cause cases of meningococcal infection severe infection of the linings of the brain and/or blood infection and other *Neisseria* infections including disseminated gonorrhoea. To reduce the risk of severe infections, you/your child will need to take certain precautions.

## You/your child must be vaccinated against *haemophilus influenzae* and pneumococcal infection

To reduce the risk of developing infection you/your child (less than 18 years):

- Must be vaccinated against *Haemophilus influenzae* and pneumococcal infections according to national vaccination guidelines at least 2 weeks before starting eculizumab therapy

Or

- If eculizumab treatment is started less than 2 weeks after you/your child receive these vaccines, then you/your child will be given antibiotics for 2 weeks after you/your child are given the vaccine.

If you/your child has not received a meningococcal vaccine or antibiotics, speak to your doctor immediately and before treatment with eculizumab begins.

If the vaccine is not suitable for you/your child (contraindicated), you/your child will be given an antibiotic throughout the treatment period.

## You will need to be aware of the signs and symptoms of:

### Severe infection

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

### Meningitis and sepsis

If you are a parent/legal guardian of an infant or child who is receiving eculizumab, it is important to be aware that signs and symptoms of meningitis and/or sepsis can vary according to your child's age.

#### In babies, additional signs and symptoms to those listed above may include:

- Rapid breathing
- Cold hands and feet
- Refusing food and/or vomiting
- Unusual crying or moaning
- Baby doesn't like being handled
- Baby is drowsy, floppy or unresponsive

#### In children, additional signs and symptoms to those listed above may include:

- Stiff neck
- Being drowsy or difficult to wake
- Irritability
- Shaking and leg pain



## WHEN SHOULD I SEEK URGENT MEDICAL ATTENTION?

Notify your doctor immediately if ANY of the aforementioned symptoms occur.

**If you cannot reach your doctor, go to an Accident & Emergency department and show them your/your child's Patient Safety Card.**

## ARE THERE SERIOUS SIDE EFFECTS WITH ECULIZUMAB?

### Allergic reactions

Notify your doctor immediately if any of the following symptoms of severe allergic reaction (anaphylaxis) occur:

- Swelling of the throat and mouth
- Difficulty breathing
- Lightheadedness
- Confusion
- Blue skin or lips
- Collapsing/losing consciousness

## WHAT DO I DO IF I/MY CHILD WANT(S) TO STOP TREATMENT?

You must not stop your treatment without medical supervision.

It is very important to make sure that you/your child do/does not miss or postpone any scheduled treatment appointments in order to continue to experience the full benefits of eculizumab therapy.

**If you or your child have been prescribed eculizumab to treat atypical haemolytic uraemic syndrome (aHUS), you need to be aware of the following:**

- If eculizumab treatment is stopped completely, or postponed (or if treatments are missed), there is a risk that one of the severe complications of your/your child's condition could occur. This complication is called thrombotic microangiopathy. Blood clots form in small blood vessels and this can lead to damage to organs, with the kidney particularly affected in aHUS.

**If you or your child have been prescribed eculizumab to treat paroxysmal nocturnal haemoglobinuria (PNH), you need to be aware of the following:**

- If eculizumab treatment is stopped completely, or postponed (or if treatments are missed), there is a risk that one of the serious features of your/your child's condition could occur. Haemolysis is a serious feature of PNH – the red cells in the blood that carry oxygen around the body break apart. Haemolysis is linked with many of the symptoms of PNH, and with an increased risk of blood clots forming in key parts of the body.

**If you plan to stop treatment with eculizumab, you need to discuss beforehand with your/your child's doctor the possible side effects and risks.**

## REPORTING SIDE EFFECTS

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▼ This medicinal product is subject to additional monitoring. This will allow for quick identification of new safety information. You can help by reporting any side effects, you may get. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet. You can also report side effects directly to HPRA Pharmacovigilance, website: [www.hpra.ie](http://www.hpra.ie).

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

### Ireland

You can report a suspected side effect in a number of ways:

- Rapid breathing
- To your doctor, pharmacist or nurse who can then notify the HPRA.
- By using the HPRA's online form.
- By downloading a copy of the HPRA's adverse reaction report form. You can e-mail completed forms to [medsafety@hpra.ie](mailto:medsafety@hpra.ie)
- By printing the HPRA's adverse reaction report form and posting a completed copy to the HPRA by freepost via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2
- By calling the HPRA on (01) 676 4971

For more details view the HPRA's Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie)

## 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: Ireland: 1800 441 100

## HOME HEALTHCARE SERVICE

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Home infusion may be considered for patients who have tolerated infusions well in the clinic. For more details, please ask your physician about this service and availability.

## 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: Ireland: 1800 441 100

## GLOSSARY OF TERMS

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### Anaphylactic reaction

Extreme and severe 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.