

Epysqli™
(Eculizumab)

Patient/Parent/Legal Guardian Guide

Drug substance 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.

This guide is to explain important safety information related to eculizumab to patients and parents/legal guardians of infants and children who are prescribed eculizumab.
Eculizumab must be prescribed by a doctor.

This document is approved by The Executive Directorate of Pharmacovigilance, at Saudi Food and Drug Authority (SFDA).

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1. INTRODUCTION

Epysqli is used to treat adults and children with:

- Paroxysmal Nocturnal Haemoglobinuria (PNH)

You will receive the following material from your doctor:

▶ **Patient Card**

- It is very important to rapidly identify and treat certain types of infection in patients who receive eculizumab; 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 eculizumab therapy and for 3 months after the last dose of eculizumab and show it to any healthcare professional you see.

▶ **Patient/Parent/Legal Guardian guide** which includes paediatric safety information card

▶ **Eculizumab Patient Information Leaflet**

2. SAFETY CONSIDERATIONS RELATED TO ECULIZUMAB

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 disabilities².**

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.
- ▶ Vaccination or revaccination may further activate complement and, as a result, patients with complement-mediated diseases may experience increased signs and symptoms of their underlying disease.

Ask your doctor if you have any questions about vaccinations 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 and fever
 - Headache with a stiff neck or stiff back
 - Fever
 - Fever and Rash
 - Confusion
 - Muscle aches with flu-like symptoms
 - Eyes sensitivity to light
- ▶ **Carry the patient card 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 health care 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.
- Before starting eculizumab, tell your doctor if you have any infections.
- If you know that you are at risk of gonorrhoea (a sexually transmitted infection), 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.
- Administer eculizumab therapy with caution to patients with active systemic infections.

Infusion/Allergic reactions

- Eculizumab contains a protein, and proteins may cause infusion or allergic reactions (including anaphylaxis) in some patients.
- If you experience any signs or symptoms such as: difficulty in breathing, swelling of the throat and mouth, dizziness, blue skin or lips, and loss consciousness after receiving eculizumab, you should consult your healthcare professional.

Blood abnormalities and cancers

- If you are a patient with PNH, you will be monitored for changes in blood cells.
- The PNH laboratory monitoring may potentially alert your doctor to blood abnormalities and cancers. The PNH laboratory monitoring continues during eculizumab treatment and for a period not less than 8 weeks after eculizumab is stopped.

Pregnancy and breast feeding

- Eculizumab is not recommended during pregnancy and in women of childbearing potential not using contraception.
- Ask your doctor for advice before using eculizumab if you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby.
- Adequate contraception during treatment and up to 5 months after treatment should be used in women who are able to get pregnant.

3. HOW LONG WILL I NEED TO TAKE ECULIZUMAB?

As you have a chronic disease, eculizumab is intended to be an ongoing therapy.

Do not stop treatment without first discussion with your doctor.

If you stop using eculizumab for PNH

Interrupting or stopping treatment with eculizumab may cause your PNH symptoms to come back more severely.

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

Your doctor will monitor you closely for at least 8 weeks.

The risks of stopping eculizumab include increased breakage of your red blood cells, which may cause:

- A significant fall in your red blood cell counts (anaemia),
- Confusion or change in how alert you are,
- Chest pain, or angina,
- An increase in your serum creatinine level (problems with your kidneys), or
- Thrombosis (blood clotting).

If you have any of the above, contact your doctor.

4. IMPORTANT SAFETY INFORMATION FOR INFANTS WHO ARE TAKING ECULIZUMAB

This section is for parents/ legal guardians of infants and young children who are receiving eculizumab.

Meningococcal infections are extremely dangerous and may become life-threatening within hours. Early symptoms of meningitis can include:^{2,3}

- 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:^{3,4}

- Fever, cold hands and feet
- Fretful, dislike being handled
- Rapid breathing or grunting
- Unusual cry, moaning
- Stiff neck, dislike 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 to those listed for infants may include:⁴

- Severe muscle pain
- Severe headache
- Confusion
- Irritability

Do not wait for a rash^{2,3}. 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.

FURTHER INFORMATION

For more information about eculizumab or in case of any safety concerns, please contact your doctor.

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

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



Or

PharmaKnowl Consulting:

Email: gppv-saudi@pharmaknowl.com

Phone: +966112777729 / +966112404409

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Version number 1.2 in January 2024