

SOLIRIS[®] (eculizumab)

Patient/Parent/Legal Guardian Guide

Paroxysmal Nocturnal Haemoglobinuria (PNH)

Atypical haemolytic Uremic Syndrome (aHUS)

Refractory Generalized Myasthenia Gravis (gMG)

Neuromyelitis Optica Spectrum Disorder (NMOSD)

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1 INTRODUCTION

Eculizumab is used to treat adults and children with:

- Paroxysmal Nocturnal Haemoglobinuria (**PNH**)
- Atypical Haemolytic Uremic Syndrome (**aHUS**)
- Eculizumab is also used to treat adult and children patients aged 6 years and above with Refractory Generalized Myasthenia Gravis (**gMG**)

Eculizumab is also used to treat adults with:

- Neuromyelitis Optica Spectrum Disorder (**NMOSD**)

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.

You will receive the following material from your doctor:

- **Patient Alert 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**
- **Eculizumab Patient Information Leaflet**

Your doctor will offer you to participate in the PNH/aHUS Registry. It is your doctor who can register you in this registry. **This is only open to patients in Great Britain.**

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 disabilities.**

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, including PNH, aHUS, refractory gMG and NMOSD may experience increased signs and symptoms of their underlying disease.

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
- ▶ **Carry the patient alert 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.**

If you cannot reach your doctor, go to an emergency department, and show them your patient alert 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 infection in the bloodstream. 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.

Infusion reaction

The treatment will be given to you by your health care provider by infusing eculizumab from a drip bag through a tube directly into your vein.

Because there is a risk of reaction during or after the infusion (including allergic reaction), you will be monitored for about one hour following each infusion. Carefully follow the doctor's instructions.

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 discussing 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 and sooner.

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 large drop in the number of red blood cells (anaemia),
- Confusion or change in how alert you are,
- Chest pain, or angina,
- Problems with your kidneys (an increase in your serum creatinine level) or
- Blood clotting (thrombosis).

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

If you stop using eculizumab for aHUS

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 an increase in inflammation and activation of 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 (anaemia),
- Problems with your kidneys;
 - decreased urination
 - 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

If you stop using eculizumab for gMG

Interrupting or stopping treatment with eculizumab may cause your gMG symptoms to come back. Do not stop treatment without first discussing with your doctor.

Your doctor will discuss the possible side effects and risks with you. Your doctor will also monitor you closely.

4 IMPORTANT SAFETY INFORMATION FOR INFANTS AND CHILDREN 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:

- 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, 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 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.

If your child shows any signs or symptoms of meningitis or severe blood infection (sepsis), contact their healthcare provider immediately.

If you cannot reach the healthcare professional, seek **immediate** emergency care at an emergency department and show the staff the Patient Alert Card.

Reporting Side Effects

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 (Great Britain and Northern Ireland)

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Alexion Pharma UK Ltd on uk.adverseevents@alexion.com or Freephone (UK): 0800 321 3902

Ireland

Health Products Regulatory Authority (HPRA)
Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland, D02 XP77

Reporting forms and information can be found at www.hpra.ie, or email: medsafety@hpra.ie.

Adverse events should also be reported to Alexion Pharma UK Ltd on uk.adverseevents@alexion.com or Freephone: 1 800 936 544

More Information

For more information about eculizumab contact: medinfo.EMEA@alexion.com or Tel: UK: 0800 028 4394 / Ireland: 1800 882 840

Home Healthcare Services

Alexion funds a Home Healthcare service, which is available to all patients prescribed with eculizumab. For more details, please ask a doctor about this service and availability.

REFERENCES

1. SOLIRIS® (eculizumab) Patient Information Leaflet available here: <https://www.medicines.org.uk/emc/>, <https://www.emcmedicines.com/en-GB/northernireland/> or <https://www.medicines.ie/>

