

SOLIRIS® (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 related to eculizumab
- ▶ Important safety information for infants and children who are receiving eculizumab

WHAT IS ECULIZUMAB

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**)

Eculizumab 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 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.
- **Guide for Patients/Parents/Caregivers**
- **Eculizumab Patient Information Leaflet**

IMPORTANT SAFETY INFORMATION 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.
- 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 gonorrhea 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 gonorrhea (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.

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 an increase in the inflammation 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),
- 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

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.

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.

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 via contactazmedical@astrazeneca.com. Alternatively, if this form is unavailable, Adverse events can be reported to patient-safety-ireland@astrazeneca.com or Tel: 1 800 936 544

More Information

For more information about eculizumab contact: medinfo.EMEA@alexion.com or Tel: 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. Eculizumab Patient Information Leaflet available here:
<https://www.medicines.ie/>

