ALEXION
AstraZeneca Rare Disease

SOLIRIS® (eculizumab)
Guide for Healthcare Professionals

The aim of this guide is to help mitigate the risk of meningococcal infection associated with the use of eculizumab and to increase awareness of the need for the required vaccinations. Please make sure to inform patients receiving eculizumab treatment of this information and ensure that they fully understand it.

It must be used in combination with the eculizumab Summary of Product Characteristics

The guide describes:

- What is eculizumab?
- Important safety information
- Adverse Event Reporting

WHAT IS ECULIZUMAB?

Eculizumab is indicated in adults and children for the treatment of:

- Paroxysmal nocturnal haemoglobinuria (**PNH**)

  Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history.
- Atypical haemolytic uremic syndrome (**aHUS**)
- Refractory generalized myasthenia gravis (**gMG**) in patients aged 6 years and above who are anti-acetylcholine receptor (AChR) antibody-positive.

Eculizumab is indicated in adults for the treatment of:

- Neuromyelitis optica spectrum disorder (**NMOSD**) in patients who are anti-aquaporin-4 (AQP4) antibody-positive with a relapsing course of the disease.

Key Actions Required

You will be provided with the following materials to be given to each patient treated with eculizumab. Please read these materials ahead of prescribing eculizumab to your patients.

- **Patient Card**

  To inform patients and healthcare providers about the risk of meningococcal infection associated with eculizumab.
- **Guide for Patients/Parents/Caregivers**

  To educate patients/parents/caregivers about the risk of meningococcal infection associated with eculizumab treatment and the need for vaccination.
- **Patient Information leaflet**

  To provide comprehensive information to patients/parents/caregivers about eculizumab.

IMPORTANT SAFETY INFORMATION

Serious Meningococcal Infection

- Due to its mechanism of action, the use of eculizumab increases the patient's susceptibility to meningococcal infection (Neisseria meningitidis).
- Cases of serious or fatal meningococcal infections have been reported in eculizumab treated patients. Meningococcal infections in patients treated with eculizumab have presented as meningococcal sepsis.

To minimise the risk of meningococcal infection and poor outcomes following infection:

Prior to starting treatment with eculizumab:

- ▶ Ensure vaccination of patients with a meningococcal vaccine at least 2 weeks prior to initiating eculizumab, unless the risk of delaying eculizumab therapy outweighs the risk of developing a meningococcal infection.
  - For patients who initiate eculizumab treatment less than 2 weeks after receiving a tetravalent meningococcal vaccine, treat with appropriate prophylactic antibiotics until 2 weeks after vaccination
- ▶ Patients must receive vaccination according to current national vaccination guidelines for vaccination use:

  https://www.hse.ie/eng/health/immunisation/

  https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-13-meningococcal-infection
- ▶ Monitor patients closely for disease symptoms after recommended vaccination as vaccination may further activate complement. As a result, patients with complement-mediated diseases, may experience increased signs and symptoms of their underlying disease.
- ▶ Since vaccination may not be sufficient to prevent meningococcal infection, consider prophylactic use of antibiotics in addition to vaccination based on the official guidance on the appropriate use of antibacterial agents.

During treatment with eculizumab:

- ▶ Monitor your patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.
- ▶ Revaccinate according to current national vaccination guidelines for vaccine use in patients treated with complement inhibitors.

INFORM PATIENTS AND CAREGIVERS/PARENTS ABOUT THE RISK OF MENINGOCOCCAL INFECTION.

Inform and educate patients that if they suspect an infection, they should seek immediate medical attention.

The relevant signs and symptoms include:

- Headache with nausea or vomiting
- Headache and a fever
- Headache with a stiff neck or stiff back
- Fever
- Fever and a rash
- Confusion
- Muscle aches with flu-like symptoms
- Eyes sensitive to light

Common Signs and Symptoms in infants include:

- 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)
- Convulsions/seizures

In children, additional signs and symptoms to those listed for infants may include:

- Severe muscle pain
- Severe headache
- Confusion
- Irritability

Explain to the patient to carry the patient card at all times throughout the duration of eculizumab therapy and for 3 months after the last dose of eculizumab and show it to any healthcare professionals they see.

Other Systemic Infections

Serious infections with Neisseria species (other than Neisseria meningitidis), including disseminated gonococcal infection, have been reported with eculizumab. Counsel patients about gonorrhea prevention and advise regular testing for patients at risk.

Patients below the age of 18 years old must be vaccinated against Haemophilus influenzae and pneumococcal infections, and strictly need to adhere to the national vaccination recommendations for each age group.

REPORTING ADVERSE EVENTS

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions.

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: 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 contact your local Alexion office via customeroperationsuk@alexion.com or Tel: +44 800 0212.

REFERENCES

1. Eculizumab SmPC available here: www.medicines.ie/

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