**Guide for Healthcare Professionals**

Drug Substance: SOLIRIS® (eculizumab)

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# Guide for Healthcare Professionals

### Important Risk Minimization Information 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.

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

The guide describes:

- What is SOLIRIS (eculizumab)?
- Important Safety information
- Adverse Event Reporting
- Contact Information

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# WHAT IS SOLIRIS (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**

# 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.

### 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
- **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 meningococcal vaccine, treat with appropriate prophylactic antibiotics until 2 weeks after vaccination.

- Patients must receive vaccinations according to current national vaccination recommendations in Saudi Arabia. Healthcare professionals should refer to the Saudi National Immunization Program (NIP) and the Saudi Food and Drug Authority (SFDA) vaccine guidance for the most current vaccination requirements and recommendations.

- 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 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 with a stiff neck or back
  - Fever
  - Rash
  - Confusion
  - Severe muscle aches combined with flu-like symptoms
  - Sensitivity to light

- **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 that they must 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 OF ADVERSE EVENTS

Adverse events should be reported to:

AstraZeneca, Saudi Arabia:

QPPV Name: Malak Alshammari

Email: ksa.ae@astrazeneca.com

Phone: +966 11 2249235

Portal: https://contactazmedical.astrazeneca.com/

Or SFDA reporting information:

Email: npc.drug@sfda.gov.sa

Toll free phone: 19999

Portal: https: //ade.sfda.gov.sa



## CONTACT INFORMATION

For more information about Eculizumab, medinfo-ksa@astrazeneca.com

## REFERENCES

SOLIRIS (eculizumab) Summary of Product Characteristics