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 SOLIRIS and to increase awareness of the need for the required vaccinations.

It must be used in combination with the SOLIRIS (eculizumab) Israeli Prescribing Information.

The guide describes:

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

WHAT IS SOLIRIS?

SOLIRIS is indicated for the treatment of patients with:

Paroxysmal nocturnal hemoglobinuria (PNH). Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history. Eculizumab has not been studied in clinical trials in patients with PNH below 11 years of age.

Atypical hemolytic uremic syndrome (aHUS).

Refractory generalized myasthenia gravis (gMG) in patients aged 6 years and above who are anti-acetylcholine receptor (AChR) antibody-positive.

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

Important Safety Information

Serious Meningococcal Infection

- Due to its mechanism of action, the use of SOLIRIS increases the patient's susceptibility to meningococcal infection (*Neisseria meningitidis*).

- Cases of serious or fatal meningococcal infections have been reported in SOLIRIS treated patients. Meningococcal infections in patients treated with SOLIRIS have presented as meningococcal sepsis.

- Soliris is contraindicated in patients who are not currently vaccinated against Neisseria meningitidis unless they receive prophylactic treatment with appropriate antibiotics until 2 weeks after vaccination.

Key Actions Required

- You will be provided with the following materials to be given to each patient treated with SOLIRIS. **Please read these materials ahead of prescribing SOLIRIS to your patients.**
    - **Patient Card**
      To inform patients and healthcare providers about the risk of meningococcal infection associated with SOLIRIS.
    - **Guide for Patients/parents/caregivers**
      To educate patients/parents/caregivers about the risk of meningococcal infection associated with SOLIRIS treatment and the need for vaccination.
    - **Patient Information leaflet**
      To provide comprehensive information to patients/parents/caregivers about SOLIRIS.

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

Prior to starting treatment with SOLIRIS:

- Ensure vaccination of patients with a meningococcal vaccine at least 2 weeks prior to initiating SOLIRIS, unless the risk of delaying SOLIRIS therapy outweighs the risk of developing a meningococcal infection.
  - For patients who initiate SOLIRIS treatment less than 2 weeks after receiving a 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 - MoH: https://www.gov.il/he/pages/vaccine-guidelines-main.

- Vaccines against serogroups A, B, C, Y, W135, are recommended in preventing the commonly pathogenic meningococcal serogroups.

- 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 SOLIRIS:

- 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.

  - In addition, instruct the parents/legal guardians not to stop the treatment without consulting with their treating physician.

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

- 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 that they must carry the patient card at all times throughout the duration of SOLIRIS therapy and for 3 months after the last dose of SOLIRIS 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 SOLIRIS. 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

Side effects can be reported to the Israeli Ministry of health by clicking on the link “Report Side Effects of Drug Treatment” that appears on the homepage of the Israeli Ministry of Health’s website (www.health.gov.il) which links to a portal, or by the following link: https://sideeffects.health.gov.il/ and by emailing the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com, Tel: 1-800-250-255.

CONTACT INFORMATION

For more information about Soliris, email: drugsafety@neopharmgroup.com

REFERENCES

SOLIRIS (eculizumab) Prescribing Information as approved by the Israeli MOH.

474-JUN-2025

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