

# **Soliris REMS**

## **Prescriber Safety Brochure**

**This brochure provides information on:**

- **The risk of meningococcal infection**
- **Patient meningococcal vaccination recommendations**
- **Monitoring Patients**
- **Counseling and providing your patients with a Patient Safety Brochure and Patient Safety Card**

## Risk of Serious Meningococcal Infections

- Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.
- Soliris is associated with an approximate 2,000-fold increased risk of meningococcal disease in comparison to the general U.S. population annual rate (0.14 per 100,000 population in 2015).

## Immunization

- **Immunize all patients with meningococcal vaccines at least 2 weeks prior to administering the first dose of Soliris**, unless the risks of delaying Soliris therapy outweigh the risks of developing a meningococcal infection.
- **Provide 2 weeks of antibacterial drug prophylaxis to patients if Soliris must be initiated immediately and vaccines are administered less than two weeks before starting Soliris therapy.**
- Do not initiate Soliris therapy in patients with unresolved serious *Neisseria meningitidis* infection or who are not currently vaccinated, unless the risks of delaying Soliris treatment outweigh the risk of developing a meningococcal infection.
- If urgent Soliris therapy is indicated in an unvaccinated patient, administer meningococcal vaccines(s) as soon as possible.
- **Vaccination reduces, but does not eliminate, the risk of meningococcal infections.**
- Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies. Revaccinate patients in accordance with ACIP recommendation, considering the duration of Soliris therapy.

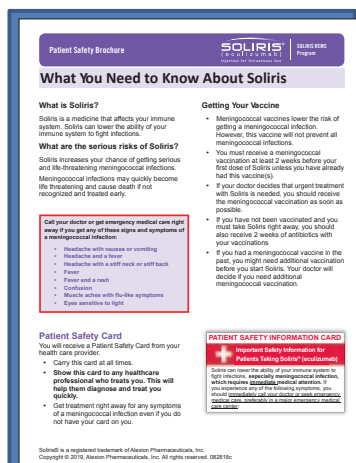
## Monitoring Patients

- Monitor patients for early signs of meningococcal infections, and evaluate immediately if infection is suspected.
- Discontinue Soliris in patients who are being treated for serious meningococcal infections

## Patient Counseling

Counsel and provide your patients with both the **Patient Safety Brochure** and **Patient Safety Card**.


- Tell your patients about the risk of meningococcal infections and that this risk may continue for several weeks after the last dose of Soliris.
- Instruct your patients to seek immediate medical attention if they develop any of the following symptoms:
  - Headache with nausea or vomiting
  - Headache with a stiff neck or stiff back
  - Fever and rash
  - Muscle aches with flu-like symptoms
  - Headache and a fever
  - Fever
  - Confusion
  - Eyes sensitive to light



## Patient Safety Card

The card has important safety guidance for both patients and any healthcare provider that may see or treat your patient for medical care.

**PATIENT SAFETY INFORMATION CARD**

 **Important Safety Information for Patients Taking Soliris® (eculizumab)**

Soliris can lower the ability of your immune system to fight infections, **especially meningococcal infection, which requires immediate medical attention.** If you experience any of the following symptoms, you should **immediately call your doctor or seek emergency medical care, preferably in a major emergency medical care center:**

- Discuss the importance and the proper use of this safety card with every patient.
- **Tell your patients to carry this card at all times.**
- Instruct patients to show the card to any healthcare professional involved in their care.

## **Soliris REMS (Risk Evaluation and Mitigation Strategy)**

A REMS is a program required by the FDA to manage known or potential serious risk associated with a drug program. Soliris is available only through a restricted program under a REMS. Healthcare providers who prescribe Soliris must be specially certified. Certification consists of review of REMS education materials and enrollment in the Soliris REMS program.



Visit [www.solirisREMS.com](http://www.solirisREMS.com) or call 1-888-SOLIRIS (765-4747) to learn more about the Soliris REMS. Enrollment can also be completed online at [www.solirisrems.com](http://www.solirisrems.com)

## **Indication and Usage**

Soliris is indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.

Soliris is indicated for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

### Limitation of Use

Soliris is not indicated for the treatment of patients with Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS).

Soliris is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Soliris is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

## **Adverse Event Experiences**

To report any suspected adverse event experience, contact Alexion Pharmaceuticals Inc. at 1.844.259.6783 or report to the FDA at 1.800.FDA.1088.

This guide does not provide all risk information for Soliris.

Please see full Prescribing Information for Soliris, including Boxed WARNING regarding serious meningococcal infection for more detailed safety information.



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