Before starting your patients on Soliris®.

Important safety information for the healthcare provider

SOLIRIS®
(eculizumab)
Injection for Intravenous Use

Prior to initiating Soliris® (eculizumab) therapy, it's important to review with patients the *Soliris Patient Safety Information Card* and instruct them to be diligent and follow the safety information. Encourage your patients to ask any questions they may have about Soliris at any time. Your patients will come to you for the answers, so provide them with the best education and support you can by becoming better acquainted with Soliris safety information.

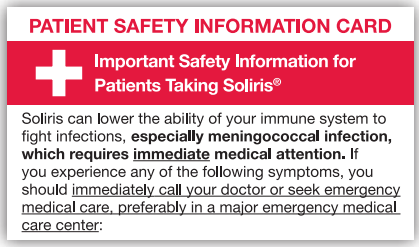
These tools are to aid you in your discussions. In our ongoing effort to maximize the safety and improve outcomes we have provided safety resources, including:

- Patient Safety Information Card
- A Soliris Medication Guide for you and your patients

Patient Safety Information Card

You are provided with Patient Safety Information Cards to give to your patients. You should discuss the importance and the proper use of this card with every patient. Patients should carry this card at all times to show to any healthcare professional involved in their care. The Patient Safety Information Card contains safety guidance for Soliris patients and their healthcare providers.

Prescribers should advise patients to seek medical attention immediately if they develop headache with nausea or vomiting, or headache and fever, even if they don't have their Patient Safety Information Card with them.


PATIENT SAFETY INFORMATION CARD

Important Safety Information for Patients Taking Soliris®

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:

SOLIRIS®
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For Discussion With Patients—Important Safety Information

MEDICATION GUIDE

Soliris® (so-leer-is)
(eculizumab)

Read the Medication Guide before you start Soliris and before each infusion. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment. Talk to your doctor if you have any questions about your treatment with Soliris.

What is the most important information I should know about Soliris?

Soliris is a medicine that affects your immune system. Soliris can lower the ability of your immune system to fight infections.

- **Soliris increases your risk of getting serious and life-threatening meningococcal infections.**

  Meningococcal infections may quickly become life-threatening and cause death if not recognized and treated early.

  1. **You must receive meningococcal vaccination at least 2 weeks before your first dose of Soliris unless you have already had this vaccine. If your doctor decides that urgent treatment with Soliris is needed, you should receive meningococcal vaccination as soon as possible.**
  2. **If you had a meningococcal vaccine in the past, you might need additional vaccination before starting Soliris. Your doctor will decide if you need additional meningococcal vaccination.**
  3. **Meningococcal vaccines do not prevent all meningococcal infections. Call your doctor or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection:**
     - **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**

Please see back cover for Important Safety Information.
Please see full prescribing information for Soliris, including boxed WARNING regarding serious meningococcal infection.

Your doctor will give you a **Patient Safety Card** about the risk of meningococcal infection. Carry it with you at all times during treatment and for 3 months after your last Soliris® dose. Your risk of meningococcal infection may continue for several weeks after your last dose of Soliris. It is important to show this card to any doctor or nurse who treats you. This will help them diagnose and treat you quickly.

Soliris is only available through a program called the Soliris REMS. Before you can receive Soliris, your doctor must:

- enroll in the Soliris REMS program
- counsel you about the risk of meningococcal infection
- give you information about the symptoms of meningococcal infection
- give you a **Patient Safety Card** about your risk of meningococcal infection, as discussed above.
- make sure that you are vaccinated with a meningococcal vaccine

Soliris may also increase the risk of other types of serious infections. If your child is treated with Soliris, make sure that your child receives vaccinations against *Streptococcus pneumoniae* and *Haemophilus influenza* type b (Hib).

What is Soliris?

Soliris is a prescription medicine called a monoclonal antibody. Soliris is used to treat people with:

- a disease called Paroxysmal Nocturnal Hemoglobinuria (PNH). PNH affects red blood cells.
- a disease called atypical Hemolytic Uremic Syndrome (aHUS). aHUS affects the blood system, kidney, and sometimes other body organs.

Soliris works by blocking part of your immune system. This can help your symptoms but it can also increase your chance for infection.

It is important that you:

- have all recommended vaccinations before you start Soliris
- stay up-to-date with all recommended vaccinations during treatment with Soliris

For Discussion With Patients—Important Safety Information (continued)

Who should not receive Soliris®?

Do not receive Soliris if you:

- have a meningococcal infection
- have not been vaccinated against meningitis infection, unless your doctor decides that urgent treatment with Soliris is needed. See "What is the most important information I should know about Soliris?"

What should I tell my doctor before receiving Soliris?

Before receiving Soliris, tell your doctor if you:

- have an infection or fever
- are pregnant or plan to become pregnant. It is not known if Soliris will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Soliris passes into your breast milk.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How will I receive Soliris?

- Soliris is given through a vein (I.V. or intravenous infusion) usually over 35 minutes in adults and 1-4 hours in pediatric patients. If you have an allergic reaction during your Soliris infusion, your doctor may decide to give Soliris more slowly or stop your infusion.
- If you are an adult, you will usually receive a Soliris infusion by your doctor:
  - — weekly for five weeks, then
  - — every 2 weeks
- If you are less than 18 years of age, your doctor will decide how often you will receive Soliris depending on your age and body weight.
- After each infusion, you should be monitored for one hour for allergic reactions. See "What are the possible side effects of Soliris?"
- If you forget or miss a Soliris® infusion, call your doctor right away.

- **If you have PNH, your doctor will need to monitor you closely for at least 8 weeks after stopping Soliris. Stopping treatment with Soliris may cause breakdown of your red blood cells due to PNH.**

  Symptoms or problems that can happen due to red blood cell breakdown include:

  — drop in the number of your red blood cell count
  — drop in your platelet count
  — confusion
  — chest pain
  — kidney problems
  — blood clots
  — difficulty breathing

- **If you have aHUS, your doctor will need to monitor you closely during and for at least 12 weeks after stopping treatment for signs of worsening aHUS symptoms or problems related to abnormal clotting (thrombotic microangiopathy).**

  Symptoms or problems that can happen with abnormal clotting may include:

  — stroke
  — confusion
  — seizures
  — chest pain (angina)
  — difficulty breathing
  — kidney problems
  — swelling in arms or legs
  — a drop in your platelet count

What are the possible side effects of Soliris?

Soliris can cause serious side effects, including:

- **See "What is the most important information I should know about Soliris?"**
- **Serious allergic reactions.** Serious allergic reactions can happen during your Soliris infusion. Tell your doctor or nurse right away if you get any of these symptoms during your Soliris infusion:

  — chest pain
  — trouble breathing or shortness of breath
  — swelling of your face, tongue, or throat
  — feel faint or pass out

  If you have an allergic reaction to Soliris, your doctor may need to infuse Soliris more slowly, or stop Soliris. See "How will I receive Soliris?"

For Discussion With Patients—Important Safety Information (continued)

Common side effects in people with PNH treated with Soliris® include:

- headaches
- runny nose and colds
- sore throat
- back pain
- nausea

Common side effects in people with aHUS treated with Soliris include:

- headache
- diarrhea
- high blood pressure
- common cold (upper respiratory infection)
- abdominal pain
- vomiting
- nasopharyngtis
- low red blood cell count
- cough
- peripheral edema
- nausea
- urinary tract infection
- pyrexia

Tell your doctor about any side effect that bothers you or that does not go away. These are not all the possible side effects of Soliris. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1.800.FDA.1088.

General information about Soliris®

Medicines are sometimes prescribed for conditions other than those listed in a Medication Guide. This Medication Guide summarizes the most important information about Soliris. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Soliris that is written for healthcare professionals.

What are the ingredients in Soliris?

Active ingredient: eculizumab

Inactive ingredients: sodium phosphate monobasic, sodium phosphate dibasic, sodium chloride, polysorbate 80 (vegetable origin) and Water for Injection.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by Alexion Pharmaceuticals, Inc.
100 College Street, New Haven, CT 06510 USA.

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Want to learn more about Soliris®?

- Visit www.Soliris.net or www.solirisrems.com
- Call 1.888.SOLIRIS (1.888.765.4747), for information regarding Soliris and the Soliris REMS.
- To report suspected Adverse Event experiences, please call Alexion Pharmaceuticals, Inc. at 1.844.259.6783

IMPORTANT SAFETY INFORMATION

WARNING: 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.

- Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies.
- Immunize 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. [see *Warnings and Precautions (5.1)* for additional guidance on the management of the risk of meningococcal infection].
- Monitor patients for early signs of meningococcal infections, and evaluate immediately if infection is suspected.

Soliris is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Soliris REMS prescribers must enroll in the program. Enrollment in the Soliris REMS program and additional information are available by telephone: 1-888-SOLIRIS (1-888-765-4747) or at solirisrems.com.

The most frequently reported adverse reactions in the PNH randomized trial (≥10% overall and greater than placebo) are: headache, nasopharyngitis, back pain, and nausea.

The most frequently reported adverse reactions in aHUS single arm prospective trials (≥20%) are: headache, diarrhea, hypertension, upper respiratory infection, abdominal pain, vomiting, nasopharyngitis, anemia, cough, peripheral edema, nausea, urinary tract infections, pyrexia.

Please see full prescribing information for Soliris, including boxed WARNING regarding serious meningococcal infection.

ALEXION®

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