

Dear Soliris® Patient,

Please carefully read this Soliris (eculizumab) OneSource Safety Support Patient Enrollment Form before you begin treatment with Soliris. Do not hesitate to ask your healthcare provider any questions regarding the information provided below. Your healthcare provider will review important safety information regarding Soliris treatment, and answer any questions you have about your treatment.

You should seek medical attention immediately if you develop a headache with nausea or vomiting, or headache and fever, even if you do not have your Soliris Patient Safety Information Card with you.

## Important safety information you should know about Soliris

- Soliris treatment lowers the ability of your immune system to fight infections
- Soliris increases your chance of getting serious and life-threatening meningococcal infections
  - As a safety precaution, you should be vaccinated against meningococcal infections before starting Soliris
  - Your healthcare provider will make sure you receive the vaccines at least 2 weeks before your first infusion, unless you have already been vaccinated, or your doctor decides that urgent treatment with Soliris is needed
  - Meningococcal vaccines do not prevent all meningococcal infections. Your doctor will provide you with the tools and information you will need to identify and take early action if you suspect that you have a meningococcal infection
- 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.

## Program materials

Your healthcare provider will provide a copy of the Soliris Medication Guide prior to you starting your treatment with Soliris. Please review this information. If you have any questions, speak with your healthcare provider.

Additionally, you will receive a Soliris Patient Safety Information Card that you should **carry on you at all times. Show this card to any doctor involved in your treatment.** This card lists the following symptoms of infection that, if experienced, **require you to contact your doctor immediately:**

- headache with nausea or vomiting
- headache with a stiff neck or stiff back
- fever and a rash
- muscle aches with flu-like symptoms
- headache and a fever
- fever
- confusion
- eyes sensitive to light

**If you cannot reach your doctor, go to an emergency room and immediately show them your Soliris Patient Safety Information Card.**

## Who should not receive Soliris?

**Do not receive Soliris if you:**

- have a meningococcal infection
- have not been vaccinated or are not up to date with a meningococcal vaccine

**Tell your doctor if you:**

- have an infection or fever
- are pregnant, become pregnant, or are breastfeeding. Soliris has not been studied in pregnant or nursing women.

## How will I receive Soliris® (eculizumab)?

Soliris is given through a vein (I.V. infusion) over 35 minutes in adults and 1-4 hours in pediatric patients.

## What are the possible side effects of Soliris?

Soliris increases your chance of getting serious and life-threatening meningococcal infections. Meningococcal infections may be fatal if not recognized and treated early.

- The most frequently reported adverse reactions in the PNH patient trials are: headache, nasopharyngitis, back pain, and nausea.
- The most frequently reported adverse reactions in aHUS patient trials are: headache, diarrhea, hypertension, upper respiratory infection, abdominal pain, vomiting, nasopharyngitis, anemia, cough, peripheral edema, nausea, urinary tract infections, pyrexia.

Common side effects with Soliris include:

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

Call your doctor if you have any of these side effects.

These are not all the side effects of Soliris. Ask your doctor for more information.

## For more information about Soliris

You can find additional information by calling Soliris OneSource Safety Support Program at 1.888.SOLIRIS (1.888.765.4747) or through the Soliris.net website.

## To Report Suspected Adverse Event Experiences

Contact your healthcare provider. To report any suspected adverse event experience, contact Alexion Pharmaceuticals Inc. at 1-844-259-6783.

## Patient or caregiver or legal guardian signature for treatment with Soliris

- I have read the information on this Voluntary Patient Enrollment form.
- I have had the opportunity to ask my healthcare provider questions about important safety information regarding Soliris treatment and understand the explanations provided.
- I understand that I must fulfill my requirements regarding vaccination and revaccination.

**My signature indicates that I have read, understood, and agree with all of the statements above.**

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PRINT NAME: Patient, Caregiver or Legal Guardian

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SIGNATURE: Patient, Caregiver or Legal Guardian

Date

Please return to Alexion by fax at 1.877.580.2596 (ALXN); e-mail to [OSSP@alexion.com](mailto:OSSP@alexion.com); or mail to:

Alexion Pharmaceuticals  
Attn: OneSource Safety Support Program  
100 College Street  
New Haven, CT 06510