### Eculizumab

**Names**  
The generic drug name is eculizumab (ek-u-liz-oo-mab). Soliris® is a brand name. There may be other names for this medication.

**How is Eculizumab Given?**  
Eculizumab is used to treat blood disorders in which the immune system destroys red blood cells, including PNH (paroxysmal nocturnal hemoglobinuria) and aHUS (atypical hemolytic uremic syndrome).

Eculizumab is given by an intravenous (IV) infusion over at least 35 minutes. Infusions are given every 1 or 2 weeks, depending on why you are taking eculizumab and the length of time you have been taking it. You may be monitored for 1 hour after each infusion to check for signs of an allergic reaction.

**How Does it Work?**  
Eculizumab is a monoclonal antibody, a type of targeted therapy. It works like your normal antibodies – by attaching to, and neutralizing, a specific target. The target here is a protein in your blood called C5.

Neutralizing C5 prevents the formation of Membrane Attack Complex (MAC). Normally, MAC plays an important role in the immune system but if it isn’t working properly, it can cause the destruction of red blood cells (hemolysis). With PNH and aHUS, decreasing the level of MAC means fewer red blood cells are destroyed.

While this medication can help decrease the destruction of red blood cells, it can also weaken your immunity against certain bacterial infections.

**What Should I Tell My Doctor Before I Begin?**  
Tell your doctor about your vaccination history and if you:
- are allergic reaction to eculizumab or have any other allergies
- have, or have recently had, any kind of infection, especially meningitis
- are taking any medications
- are pregnant or breastfeeding

This drug may interact with other medications or cause harmful side effects. Tell your doctor/pharmacist about all your prescription and nonprescription medications, vitamins, and herbal supplements.
What Are Some Possible Side Effects?

- High blood pressure
- Diarrhea
- Headache
- Nausea, vomiting
- Aches and pains in back, arms, or legs
- Low white blood cell count
- Sore throat, cough, stuffy nose
- Dizziness, fatigue

How Can I Manage These Side Effects?

- Drink 2-3 quarts of fluid, especially water, every 24 hours, unless otherwise directed by your doctor.
- If you develop nausea, vomiting, or headache, ask your doctor about medication to help prevent or treat these side effects.
- Eating small, frequent meals and avoiding spicy/greasy foods may help with nausea.
- Acetaminophen (Tylenol®) and ibuprofen (Advil®/Motrin®) may help with discomfort. Talk to your doctor before taking any medication.
- Alcohol should be limited or avoided. Talk to your doctor.
- Avoid unnecessary or prolonged exposure to sunlight. Wear SPF30 or higher sunscreen, protective clothing, and sunglasses.

When Should I Call the Doctor?

Call your doctor immediately if you have:

- fever of 100.4°F (38°C) or fever with a rash
- headache with nausea or vomiting, or with a fever, or with a stiff neck or a stiff back
- signs of allergic reaction: chest pain, feeling faint, rash, hives, swelling (eyes, face, lips, tongue, throat), hoarseness, difficulty breathing or swallowing
- confusion
- muscle aches with flu-like symptoms
- developed a sensitivity to light (eyes hurt in bright light)

Call your doctor within 24 hours if you have any of the following:

- diarrhea or vomiting 4-6 times in a 24-hour period
- nausea not relieved by prescribed medication or that prevents you from eating or drinking
- yellowing of the whites of your eyes or your skin
- urine turns dark or brown
- swelling of feet or ankles, sudden weight gain
- unusual bruising, bleeding, dark colored stools, blood in the urine
What Else Should I Know About Eculizumab?

- Eculizumab increases your risk of serious meningococcal infections, an infection that may affect the covering of your brain and spinal cord and/or may spread through the bloodstream. It is recommended you get the meningococcal vaccine at least 2 weeks before their first dose of eculizumab.
  - The vaccine decreases your risk but there is still a possibility getting a meningococcal infection.
  - If you had a meningococcal vaccine in the past, you might need a booster dose before starting eculizumab.
  - If treatment with eculizumab is urgent and you cannot have the meningococcal vaccine 2 weeks before starting eculizumab, we will prescribe antibiotics to take for 2 weeks beyond when you do get the vaccine. The will decrease your risk of meningitis.
  - Your doctor will give you a patient safety card about the risk of developing meningitis. Carry this card with you at all times during treatment and for 3 months afterwards. Show it to all healthcare providers who treat you so that they will know about your risk.
  - A program called Soliris REMS has been set up to decrease the risks of receiving eculizumab injection. You can only receive eculizumab injection from a doctor who has enrolled in this program, has talked to you about the risks of meningococcal disease, has given you a patient safety card, and has made sure that you received a meningococcal vaccine.

- Eculizumab may increase your risk of streptococcal and/or haemophilus infections. Talk to your doctor about your benefits/risks of being vaccinated against these bacteria.

- Because you may be at higher risk of infection, avoid people with colds or other illnesses. Report fever or any other signs of infection to your doctor immediately. Wash your hands often. Get your doctor’s OK before you get any kind of immunization (vaccine). We recommend your vaccines be brought up to date before you begin this medication.

- There is a possibility you may have an infusion and/or allergic reaction. If you do, your nurse may slow or stop your infusion.

- Both men and women should use 2 kinds of contraceptives to avoid conceiving a child while taking eculizumab. Barrier methods such as condoms are recommended.
• Regular blood tests are necessary during treatment to determine if eculizumab is effective for you.
• Sudden discontinuation of treatment with eculizumab may cause a sudden and serious breakdown of your red blood cells. If it is necessary to stop eculizumab, your doctor will need to monitor you closely for at least 8 weeks after stopping therapy. Suddenly discontinuing this medication can cause a serious breakdown of your red blood cells.
• If you have questions about eculizumab, talk to your doctor or pharmacist.