

4.7. Medication Guide

MEDICATION GUIDE
Soliris[®] (eculizumab)
(so-leer-is)

Read the Medication Guide before you start Soliris and before each dose (infusion). This Medication Guide does not take the place of talking with your doctor about your 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 chance of getting serious and life-threatening meningococcal infections. . Meningococcal infection may be fatal if not recognized and treated early.**
- 1. **You must receive a meningococcal vaccine at least 2 weeks before your first dose of Soliris unless you have already had this vaccine.**
- 2. **If you had a meningococcal vaccine in the past, you might need a booster dose before starting Soliris.** Your doctor will decide if you need another dose of a meningococcal vaccine.
- 3. **A meningococcal vaccine does not prevent all meningococcal infections. You must be aware of the following 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 of 103° F (39.4° C) or higher**
 - **Fever and a rash**
 - **Confusion**
 - **Severe muscle aches with flu-like symptoms**
 - **Sensitivity to light**

Call your doctor or get emergency medical care right away if you have any of these symptoms.

You will receive a Patient Safety Card that lists these symptoms and what to do if you have them. Carry it with you at all times. It is important to show this card to any healthcare provider who treats you. Even if you stop using Soliris, keep this card with you for 3 months after the last Soliris dose, since side effects may occur a long time after your last dose of Soliris.

What Is Soliris?

Soliris is a medicine called a monoclonal antibody. Soliris is used for the treatment of patients with a disease that affects red blood cells called Paroxysmal Nocturnal Hemoglobinuria (PNH).

Soliris works by blocking part of your immune system. This can help your PNH symptoms but it can also increase your chance for infection. **It is important that you:**

- have all recommended immunizations and vaccines before you start Soliris
- stay up-to-date with all recommended immunizations and vaccines during treatment with Soliris

Who Should Not Receive Soliris?

Do not receive Soliris if you:

- have a meningococcal infection
- have not been vaccinated with, or you are not up-to-date with a meningococcal vaccine. See “What is the most important information about Soliris?”

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 Do I Receive Soliris?

- Soliris is given through a vein (I.V. infusion) over 35 minutes.
- You will usually receive a Soliris infusion:
 - every 7 days for five weeks, then
 - every 14 day
- Following each infusion, you may be monitored for one hour for allergic reactions.

What If I Miss a Dose or Stop Soliris Treatment?

- If you forget or miss a Soliris infusion, call your doctor right away.
- Stopping treatment with Soliris may cause a sudden and serious breakdown of your red blood cells. Symptoms or problems from red blood cell breakdown include:
 - a large drop in your red blood cell count causing anemia
 - confusion
 - chest pain
 - kidney problems
 - blood clots
- Your doctor will need to monitor you closely for at least 8 weeks after stopping Soliris.

What Are The Possible Side Effects With Soliris?

Serious side effects with Soliris include:

- **Serious and life-threatening infections.** See “What is the most important information I should know about Soliris?”

Common side effects with Soliris include:

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

Call your doctor if you have any of these side effects. These are not all the side effects with Soliris. Ask your doctor for more information.

General Information About Soliris

Medicines are sometimes prescribed for conditions other than those listed in a Medication Guide. If you have any concerns about Soliris, ask your doctor. Your doctor or pharmacist can give you information about Soliris that was written for health care professionals.

Soliris contains eculizumab in a solution of water, polysorbate, sodium phosphate and sodium chloride.

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