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MEDICATION GUIDE

Soliris (eculizumab)

(so-leer-is)

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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.

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What Is The Most Important Information I Should Know About Soliris?

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

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

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1. **You must receive a meningococcal vaccine at least 2 weeks before your first dose of Soliris unless you have already had this vaccine.**

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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.

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3. **A meningococcal vaccine does not prevent all meningococcal infections. You must be aware of the following signs and symptoms of a meningococcal infection:**

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- **moderate to severe headache with nausea or vomiting**
- **moderate to severe headache and a fever**
- **moderate to severe 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, and eyes sensitive to light**

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

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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. You will need to show the card to any healthcare provider that treats you.

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What Is Soliris?

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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).

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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:**

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

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Who Should Not Receive Soliris?

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Do not receive Soliris if you:

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

345 **Tell your doctor if you:**

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

349 **How Do I Receive Soliris?**

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

355 **What If I Miss a Dose or Stop Soliris Treatment?**

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

365 **What Are The Possible Side Effects With Soliris?**

366 **Serious side effects with Soliris include:**

- 367 • **serious and life-threatening infections.** See “What is the most important information I
368 should know about Soliris?”
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370 **Common side effects with Soliris include:**

- 371 • headaches
372 • runny nose and colds
373 • sore throat
374 • back pain
375 • nausea

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

378 **General Information About Soliris**

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

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

384 Manufactured by Alexion Pharmaceuticals, Inc., 352 Knotter Drive, Cheshire, CT 06410
385 USA.

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