

Eculizumab (Soliris®)

About This Drug

Eculizumab is used to treat some blood disorders. It is given in the vein (IV).

Possible Side Effects

- Decrease in red blood cells (you may feel more tired)
- Nausea and vomiting (throwing up)
- Pain in your abdomen
- Diarrhea (loose bowel movements)
- Fever
- Swelling of your legs, ankles and/or feet
- Urinary tract infection
- Headache
- Back pain
- Muscle and bone pain
- Cough and upper respiratory infection
- Inflammation of the nasal passages and throat
- High blood pressure

Note: Each of the side effects above was reported in 10% or greater of patients treated with eculizumab. Not all possible side effects are included above.

Warnings and Precautions

- Severe infections, including bacterial and fungal
- Increased risk of severe meningitis, which can be life-threatening
- While you are getting this drug in your vein (IV), you may have a reaction to the drug. Sometimes you may be given medication to stop or lessen these side effects. Your nurse will check you closely for these signs: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. **These reactions may happen after your infusion. If this happens, call 911 for emergency care.**

- Breakdown of your red blood cells can happen once you have completed your treatment, which may cause anemia and other complications. You will be followed closely by your doctor for several weeks after your treatment has ended.

Note: *Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team*

Important Information

- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- Meningococcal vaccination is required at least 2 weeks prior to receiving treatment with eculizumab. Talk to your doctor and/or nurse about vaccination.
- You will need to sign up for a special program called Soliris® REMS when you start taking this drug. Your nurse will help you get started.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have loose bowel movements, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop your diarrhea.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- Infusion reactions may occur after your infusion. **If this happens, call 911 for emergency care.**

Food and Drug Interactions

- There are no known interactions of eculizumab with food.
- This drug may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Headache that does not go away
- Blurry vision or other changes in eyesight
- Symptoms of meningitis: headache with stiff neck and/or back, headache with nausea and vomiting, headache and a fever, fever, rash, confusion and sensitivity to light
- Wheezing or trouble breathing
- Coughing up yellow, green, or bloody mucus
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Pain in your abdomen that does not go away
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of your legs, ankles, and/or feet
- Pain or burning when you pass urine
- Difficulty urinating
- Feeling like you have to pass urine often, but not much comes out when you do
- Tender or heavy feeling in your lower abdomen
- Cloudy urine and/or urine that smells bad
- Pain on one side of your back under your ribs. This is where your kidneys are.
- Pain that does not go away, or is not relieved by prescribed medicines
- Signs of infusion reaction: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. **If this happens, call 911 for emergency care.**
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** It is not known if this drug may harm an unborn child. For this reason, be sure to talk with your doctor if you are pregnant or planning to become pregnant while receiving this drug. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** It is not known if this drug passes into breast milk. For this reason, women should talk to their doctor about the risks and benefits of breastfeeding during treatment with this drug because this drug may enter the breast milk and cause harm to a breastfeeding baby.

- **Fertility warning:** Human fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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