

Eculizumab-xxxx (Soliris, Bkemy)

About This Medicine

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

Possible Side Effects

- Decrease in red blood cells. This may make you 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
- Cough and upper respiratory tract 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-xxxx. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

- Risk of severe meningitis and other life-threatening infections, including gonorrhea in certain patients and fungal infections in patients with a weakened immune system.
- While you are getting this medicine in your vein (IV), you may have a reaction to the medicine. Sometimes you may be given medicine 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 (decreased red blood cells) and other complications. You will be followed closely by your doctor for several weeks after your treatment has ended.
- Damage to small blood vessels can happen once you have completed your treatment, which can cause bleeding and blood clots and can be life threatening. 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

- Cytotoxic medicines leave the body through urine and stool, but they can also be present in other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.
- Meningococcal vaccination is required at least 2 weeks prior to receiving treatment with eculizumab-xxxx or as soon as possible if urgent therapy is needed. If you need urgent therapy, you should also receive 2 weeks of antibiotics and receive your vaccination as soon as possible. Talk to your doctor and/or nurse about vaccination. Vaccination may not prevent serious infection.
- Certain people may be at risk of serious infections with gonorrhea. Talk to your doctor and/or nurse about whether you are at risk for gonorrhea infection, about gonorrhea prevention, and regular testing.
- You will need to sign up for a special program called Ultomiris and Soliris REMS when you start taking this medicine. Your nurse will help you get started.
- You will be given a Soliris Patient Safety Card with information about the risk of meningococcal infection that you should carry with you at all times during treatment and for three months after your last Soliris dose. Show this card to any doctor or nurse who treats you.

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 enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, 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 Medicine Interactions

- There are no known interactions of eculizumab-xxxx with food.
- This medicine 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
- Signs of meningitis: severe headache, a stiff and painful neck, fever, vomiting, feeling very sleepy, confusion, seizures, and/or sensitivity to light, rash
- Wheezing and/or trouble breathing
- Cough that is bothersome
- 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
- Signs of a urinary tract infection such as burning or pain when you pass urine, difficulty urinating, smelly and/or cloudy urine, pain in your lower abdomen or lower/side of your back.
- Easy bleeding or bruising
- Decreased or very dark urine
- Yellowing of the eyes or skin
- Pain that does not go away, or is not relieved by prescribed medicines
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, difficulty urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- Abnormal discharge from the penis or vagina



- 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

Reproduction Warnings

- **Pregnancy warning:** It is not known if this medicine 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 medicine. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** It is not known if this medicine passes into breast milk. For this reason, women should talk to their doctor about the risks and benefits of breastfeeding during treatment with this medicine because this medicine may enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Fertility studies have not been done with this medicine. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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