

Eculizumab-xxxx (Soliris, Bkembv, Epysqli)

About This Medicine

ECULIZUMAB (ek yoo LYE zyoo mab) treats certain blood conditions that can cause low levels of red blood cells (anemia) and blood clots, such as atypical hemolytic uremic syndrome (aHUS) and paroxysmal nocturnal hemoglobinuria (PNH). It works by slowing down an overactive immune system, which reduces the breakdown of red blood cells. It also prevents blood cells (platelets) from forming a clot. It is given in the vein (IV).

This medicine may be used for other purposes; ask your care team if you have questions.

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 people 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 care 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 care team 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 care team 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 care team 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 care team.*

Important Information

- This medicine may be present in the urine, stool and 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 care team after your treatment. If you take a pill each day, follow these precautions every day.
- This medicine is part of a REMS program, which helps make sure it is used safely. Your care team will follow certain steps to protect your health. You may be asked to read safety information or complete certain tests while taking it. Your care team will provide you with more information.
- 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 care team about vaccination. Vaccination may not prevent serious infection.
- Certain people may be at risk of serious infections with gonorrhea. Talk to your care team about whether you are at risk for gonorrhea infection, about gonorrhea prevention, and regular testing.
- You will be given a 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 care team 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 care team 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 care team 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 care team 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 care team 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 care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call Your Care Team

Call your care team 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
- 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, trouble 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, trouble 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.**

Reproduction Warnings

- **Pregnancy warning:** Talk with your care team if you are pregnant or planning to become pregnant while taking this medicine. Tell your care team right away if you think you might be pregnant.
- **Breastfeeding warning:** Talk with your care team about breastfeeding during treatment. You may need to stop breastfeeding.
- **Fertility warning:** The effect of this medicine on fertility is not known. If you plan to have children, talk with you care team.

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