Sutimlimab

Patient Education Sheets

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is used for a type of blood disorder called cold agglutinin disease (CAD).
- It may also be used for other reasons.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Sutimlimab (soo-TIM-li-mab): Enjaymo (en-jaye-moe)	Blocks a part of the immune system that destroys red blood cells.	Infusion into a vein (intravenous (IV) infusion).

Treatment Administration and Schedule

Treatment is typically repeated every week for the first 2 weeks, then every 2 weeks thereafter.

Weeks 1 and 2

- Sutimlimab is given once a week on Day 1.

Treatment Name	Week 1							Week 2
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 1
Sutimlimab	✓							✓

Weeks 3 and Beyond

- Sutimlimab is given once every 2 weeks on Day 1.

Treatment Name	Week 3							Next Week
	Day 1	Day 2	Day 3	Day 4	Day 5	…	Day 14	Day 1
Sutimlimab	✓							✓

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Appointments

Appointments may include regular check-ups with your care team, treatment appointments, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss an appointment, call your care team as soon as possible to reschedule it.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Given at the Clinic or Hospital	Supportive Care Taken at Home
To help lower the risk of infections		
Other		

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Common Side Effects

Side Effect	Important Information
Infections	Description: Treatment may increase your chance of getting an infection. Recommendations: • Wash your hands often and bathe regularly. • Avoid crowded places and close contact with people who are sick. • Keep any catheter/port site clean and dry. Follow all instructions provided by your care team. Talk to your care team if you have: • Fever of 100.4°F (38°C) or higher • Chills • New or worsening cough or sore throat • Painful urination or signs of a urinary infection • Feeling much more tired than usual • Red, swollen, warm, or painful areas on the skin (possible skin infection)
Fatigue	Description: Fatigue is a constant and sometimes strong feeling of tiredness. Recommendations: • Routine exercise can help reduce fatigue. Talk with your care team to find the right type and amount of activity for you. • Ask family and friends for help with daily tasks and for emotional support. • Try healthy ways to feel better, such as meditation, journaling, yoga, or guided imagery, to reduce anxiety and improve well-being. • Aim for 7 to 8 hours of sleep each night. Limit daytime naps to help you sleep better at night. • Do not drive, operate heavy machinery, or do other potentially dangerous activities if you are very tired. Talk to your care team if you have: • Tiredness that affects your daily life or prevents you from doing normal activities • Tiredness that does not get better with rest • Dizziness or weakness along with severe tiredness
Dizziness	Description: Dizziness may make you feel lightheaded, unsteady, or like you or your surroundings are spinning. Recommendations: • Sit or lie down if you feel dizzy until the feeling goes away. • Get up slowly when moving from a sitting or lying position. • Drink plenty of fluids unless your care team tells you otherwise. • Avoid driving, operating heavy machinery, or doing activities that could be dangerous if you feel dizzy. • Ask for help when walking or moving around if you feel unsteady to help prevent falls. Talk to your care team if you have: • New or worsening dizziness • Dizziness that does not go away or keeps coming back • Trouble walking or keeping your balance • Dizziness that interferes with your daily activities

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Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Red Blood Cell Breakdown (Hemolysis)	Stopping or interrupting treatment with sutimlimab may cause your red blood cells to break down, a condition called hemolysis. This may cause your red blood cell counts to decrease and symptoms of cold agglutinin disease to return. • New or worsening tiredness or weakness • Shortness of breath • Fast or pounding heartbeat • Dark or reddish-colored urine
Infusion-Related Reactions	Your care team may slow or temporarily stop the infusion if you have a reaction. Treatment may be permanently stopped for a severe reaction. • Chills or shaking • Itching, rash, or flushing • Trouble breathing, wheezing, or tongue swelling • Dizziness or feeling faint • Feeling of impending doom • Fever of 100.4°F (38°C) or higher • New or severe pain in your back or neck
Autoimmune Problems	Sutimlimab may increase your risk of developing an autoimmune disease, such as systemic lupus erythematosus (SLE). An autoimmune disease happens when your immune system mistakenly attacks healthy cells and tissues in your body. • New or worsening joint pain or swelling • Rash on your cheeks and nose • Unexplained fever

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body.** However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment may **harm an unborn baby**.
    - If you are able to become pregnant:
        - Your care team will verify your pregnancy status before treatment.
        - Use an effective method of birth control during treatment with sutimlimab.
        - If you think you might be pregnant or if you become pregnant, tell your care team right away.
    - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment with sutimlimab.
- It is **not known** if sutimlimab is present in **breast milk**. Talk with your care team if you are breastfeeding or plan to breastfeed.

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Additional Information

- **Tell your care team about all the medicines you take**.
  This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
  - Sutimlimab may increase your risk of serious infections. You should be up to date on your vaccines for pneumonia (pneumococcal) and meningitis (meningococcal) at least 2 weeks before starting treatment. If you need to start treatment right away, you should receive these vaccines as soon as possible. Ask your care team if you are not sure.
- **This Patient Education Sheet may not describe all possible side effects.**
  Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

Updated Date: November 10, 2026

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Patient Education Sheets

Scan the QR code below to access this education sheet.

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