Enjaymo®
sutimlimab-jome
Injection for intravenous use
1100 mg/22 mL

INFUSION GUIDE

ENJAYMO, the first and only approved treatment for Cold Agglutinin Disease[1]

ENJAYMO is indicated for the treatment of hemolysis in adults with Cold Agglutinin Disease.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ENJAYMO is contraindicated in patients with known hypersensitivity to sutimlimab-jome or any of the inactive ingredients.

Please see Important Safety Information on pages 9-10 and full Prescribing Information.

CAD is a chronic condition characterized by complement-mediated destruction of red blood cells, causing unpredictable and potentially severe anemia[2]

Epidemiology[3]

- Up to 16 people per 1,000,000 are impacted by CAD
- Average age of onset is ≈60 years, but CAD has been seen in some patients as young as 30 years

Common symptoms[4-8]


Anemia


Shortness of breath


Chronic hemolysis (destruction of RBCs)


Circulatory symptoms (acrocyanosis, Raynaud's phenomenon)


Hemoglobinuria


Jaundice


Livedo reticularis (rarely)


Profound fatigue

CAD=Cold Agglutinin Disease; RBC=red blood cell.

ENJAYMO administration information[1]

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Patients can receive an infusion 3 ways, subject to coverage requirements and physician determination: **in office, at an infusion center, or at home**.

BEFORE INITIATION

Complete or update vaccination against encapsulated bacteria, including *Streptococcus pneumoniae* and *Neisseria meningitidis* (serogroups A, C, W, Y and B), according to current ACIP recommendations for patients receiving complement inhibitors at least 2 weeks prior to initiation of ENJAYMO.

If urgent ENJAYMO therapy is indicated in a patient who is not up to date with vaccines for *Streptococcus pneumoniae* and *Neisseria meningitidis* administer these vaccines as soon as possible.

Vaccination does not eliminate the risk of serious encapsulated bacterial infections.

DURING INFUSION

Monitor for infusion-related reactions like shortness of breath, rapid heartbeat, nausea, flushing, headache, hypotension, chest discomfort, pruritus, rash, injection-site reaction, and dizziness.

Slow or stop the infusion if an infusion reaction occurs and institute appropriate supportive measures if signs of hypersensitivity reactions occur.

AFTER INFUSION

Following initial infusion, monitor for 2 hours for signs or symptoms of an infusion and/or hypersensitivity reaction.

For subsequent ENJAYMO infusions, monitor for 1 hour for signs of an infusion reaction.

ACIP=Advisory Committee on Immunization Practices.

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Dosing once every 2 weeks with ENJAYMO[1]

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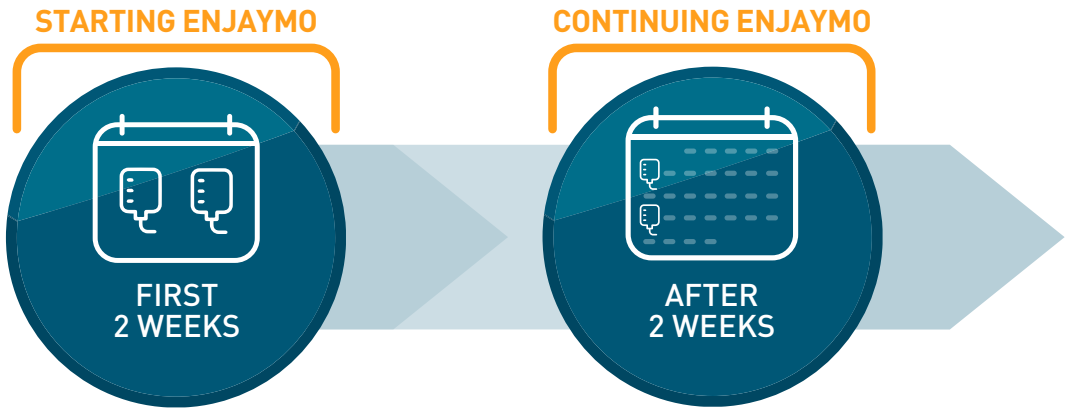
The recommended dosing regimen for adults with CAD consists of an initial dose and a dose 1 week later, followed by 1 dose every 2 weeks

Administer ENJAYMO at the recommended dosage regimen time points or within 2 days of these time points



WEIGHT-BASED INFUSION

6500 mg FOR PATIENTS 39 kg TO <75 kg

7500 mg FOR PATIENTS ≥75 kg

Interruptions in ENJAYMO treatment

- If a dose is missed, administer as soon as possible and resume dosing every 2 weeks
- If the duration after the last dose exceeds 17 days, administer weekly for 2 weeks, with administration every 2 weeks thereafter

Staying on therapy matters—stopping ENJAYMO resulted in recurrent hemolysis and anemia[1]

Please see Important Safety Information on pages 9-10 and full Prescribing Information.

Determine the appropriate dose and infusion rate for your patients receiving ENJAYMO[1]

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ENJAYMO is supplied as one 1100 mg/22 mL (50 mg/mL) single-dose vial per carton. ENJAYMO can either be administered via an undiluted or diluted preparation.

Dosing and infusion rate reference table for ENJAYMO undiluted[1]

Body weight range	Dose	ENJAYMO vials needed	ENJAYMO volume	Maximum infusion rate
39 kg to <75 kg	6500 mg	6	130 mL	130 mL/hour*
≥75 kg	7500 mg	7	150 mL	150 mL/hour*

Dosing and infusion rate reference table for ENJAYMO diluted in saline[1]

Body weight range	Dose	ENJAYMO vials needed	ENJAYMO volume	NaCl diluent volume	Total volume	Maximum infusion rate
39 kg to <70 kg	6500 mg	6	130 mL	370 mL	500 mL	250 mL/hour
70 kg to <75 kg	6500 mg	6	130 mL	370 mL	500 mL	500 mL/hour*
≥75 kg	7500 mg	7	150 mL	350 mL	500 mL	500 mL/hour*

Slow or stop the infusion in case of infusion reaction during ENJAYMO administration

*Patients with cardiopulmonary disease should receive the infusion over 120 minutes.

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Important Safety Information (continued)

WARNINGS AND PRECAUTIONS (continued)

Infusion-Related Reactions

- Administration of ENJAYMO may result in infusion-related reactions. In the two phase 3 trials, 29% (19/66) of patients treated with ENJAYMO experienced infusion-related reactions. One patient permanently discontinued ENJAYMO due to an infusion-related reaction.
- Monitor patients for infusion-related reactions and interrupt if a reaction occurs.
- Discontinue ENJAYMO infusion and institute appropriate supportive measures if signs of hypersensitivity reactions, such as cardiovascular instability or respiratory compromise, occur.

Risk of Autoimmune Disease

- Based on its mechanism of action, ENJAYMO may potentially increase the risk for developing autoimmune diseases such as systemic lupus erythematosus (SLE). Development of SLE has been associated with inherited classical complement deficiency.
- In clinical trials, 4.5% (3/66) of patients developed a relapse or worsening of previously diagnosed autoimmune disease.
- Monitor ENJAYMO patients for signs and symptoms and manage medically.

Recurrent Hemolysis After ENJAYMO Discontinuation

- If treatment with ENJAYMO is interrupted, closely monitor patients for signs and symptoms of recurrent hemolysis, eg, elevated levels of total bilirubin or lactate dehydrogenase (LDH) accompanied by a decrease in hemoglobin, or reappearance of symptoms such as fatigue, dyspnea, palpitations, or hemoglobinuria. Consider restarting ENJAYMO if signs and symptoms of hemolysis occur after discontinuation.

ADVERSE REACTIONS

- The most common adverse reactions in the CADENZA trial (Part A) (incidence ≥18%) are rhinitis, headache, hypertension, acrocyanosis, and Raynaud's phenomenon. The most common adverse reactions in the CARDINAL trial (incidence ≥25%) are urinary tract infection, respiratory tract infection, bacterial infection, dizziness, fatigue, peripheral edema, arthralgia, cough, hypertension, and nausea.

Please see full Prescribing Information.