

ENJAYMO is the **FIRST AND ONLY**
FDA-approved treatment for hemolysis in
adults with Cold Agglutinin Disease (CAD)

Cold Agglutinin
Disease pressed
PAUSE
on your life

See if ENJAYMO
can help you hit
RESUME

Lonnie, a patient on ENJAYMO

What is ENJAYMO?

ENJAYMO® is a prescription medicine used to treat the breakdown of red blood cells (hemolysis) in adults with cold agglutinin disease (CAD).

It is not known if ENJAYMO is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Do not receive ENJAYMO if you are allergic to sutimlimab-jome or any of the ingredients in ENJAYMO.

ENJAYMO can cause serious side effects, including:

- **Serious Infections:** ENJAYMO is a prescription medicine that affects your immune system. ENJAYMO may lower the ability of your immune system to fight infections. ENJAYMO increases your chance of getting serious infections including those caused by encapsulated bacteria, including *Neisseria meningitidis*, *Streptococcus pneumoniae*, and *Haemophilus influenzae* type B. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.
 - You must complete or be up to date with the vaccines against *Streptococcus pneumoniae* and *Neisseria meningitidis* at least 2 weeks before your first dose of ENJAYMO.
 - If your healthcare provider decides that urgent treatment with ENJAYMO is needed, you should receive vaccinations as soon as possible.
 - If you have been vaccinated against these bacteria in the past, you might need additional vaccines before starting ENJAYMO. Your healthcare provider will decide if you need additional vaccines.
 - Vaccines do not prevent all infections caused by encapsulated bacteria. Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a serious infection: fever with or without shivers or chills, fever with chest pain and cough, fever with high heart rate, headache and fever, confusion, clammy skin, fever and a rash, fever with breathlessness or fast breathing, headache with nausea or vomiting, headache with stiff neck or stiff back, body aches with flu-like symptoms, and/or eyes sensitive to light.

Please see Important Safety Information throughout and full [Prescribing Information](#) and [Medication Guide](#).

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You can find all of this information
and more at [ENJAYMO.com](https://www.enjaymo.com)



Nancy, a patient on **ENJAYMO**

IMPORTANT SAFETY INFORMATION (continued)

- **Infusion-related reactions:** Treatment with ENJAYMO may cause infusion-related reactions, including allergic reactions that may be serious or life-threatening. Your healthcare provider may slow down or stop your ENJAYMO infusion if you have an infusion-related reaction and will treat your symptoms if needed. Tell your healthcare provider right away if you develop symptoms during your ENJAYMO infusion that may mean you are having an infusion-related reaction, including: shortness of breath, decrease in blood pressure, chest discomfort, rapid heartbeat, nausea, injection site reaction, flushing, headache, dizziness, rash, and itchy skin.

Please see Important Safety Information throughout and full [Prescribing Information](#) and [Medication Guide](#).

What is Cold Agglutinin Disease?

Learning how Cold Agglutinin Disease (CAD) affects your body and how to recognize common symptoms may help you and your healthcare provider better manage your Cold Agglutinin Disease.

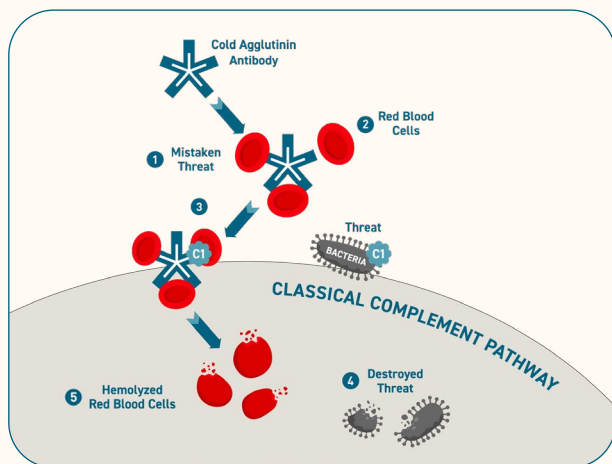
Cold Agglutinin Disease is an autoimmune hemolytic anemia with complement-mediated red blood cell destruction, in which a part of the immune system known as the complement system mistakenly attacks and destroys red blood cells in a process called **hemolysis**. Cold Agglutinin Disease can affect people as young as 30, but usually affects people 50 to 70 years of age.



Lynn, a patient on ENJAYMO

“When people look at you they can’t tell that anything is wrong. Maybe they think you’re tired or lazy, or just getting older, but that is not the case.”

—NANCY, LIVING WITH COLD AGGLUTININ DISEASE (CAD)



How does hemolysis happen?

- 1 In Cold Agglutinin Disease, the body makes **cold agglutinin antibodies** that mistakenly identify your own red blood cells as a threat.
- 2 When the cold agglutinin antibodies encounter red blood cells, they attach to the surface, causing them to **clump together** (called **agglutination**).
- 3 When the red blood cells are bound to the cold agglutinin antibodies, they form a complex that signals for the activation of the **classical complement pathway** through a protein called C1.
- 4 For those who do not have CAD, C1 is activated when antibodies bind to foreign threats, like bacteria.
- 5 The **C1** binds to the surface of the red blood cells and starts a chain of events that ends with the **destruction of the red blood cells**, or **hemolysis**.

IMPORTANT SAFETY INFORMATION (continued)

- **Risk of autoimmune disease:** ENJAYMO may increase your risk for developing an autoimmune disease such as systemic lupus erythematosus (SLE). Tell your healthcare provider and get medical help if you develop any symptoms of SLE, including: joint pain or swelling, rash on the cheeks and nose, and unexplained fever.

Please see Important Safety Information throughout and full [Prescribing Information](#) and [Medication Guide](#).

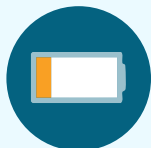
Nancy, a patient on ENJAYMO



Symptoms of Cold Agglutinin Disease can interrupt your life

When the rate of hemolysis, or red blood cell destruction, is faster than the rate at which the body makes new red blood cells, the result is low levels of red blood cells (anemia).

Symptoms caused by complement activation:



FATIGUE



NOT ENOUGH BLOOD CELLS TO CARRY OXYGEN (ANEMIA)



SHORTNESS OF BREATH



YELLOWING OF SKIN OR EYES (JAUNDICE)



DARK URINE

Symptoms caused by the cold:



BLUISH OR REDDISH DISCOLORATION



DECREASED BLOOD FLOW TO FINGERS AND TOES (RAYNAUD'S PHENOMENON)



NET-LIKE PATTERN OF REDDISH-BLUE SKIN DISCOLORATION



SKIN ULCERS OR SKIN DEATH



PAIN OR DISCOMFORT SWALLOWING COLD FOOD OR LIQUIDS

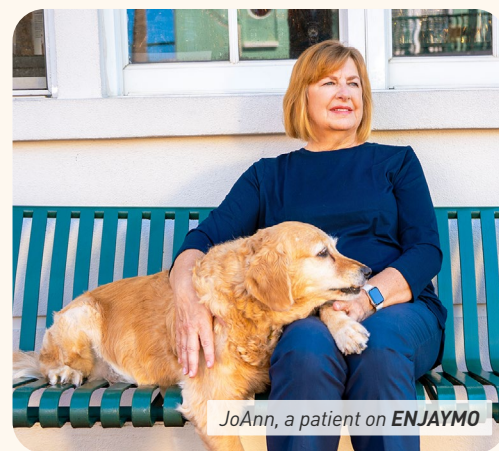
What causes certain symptoms of CAD?

Red blood cells are vital for carrying oxygen and carbon dioxide to and from your organs and tissues. With fewer red blood cells moving around your body due to hemolysis, less oxygen is delivered to your organs and tissues. This can make you feel weak, short of breath, or even make thinking or concentrating difficult. In addition to red blood cell destruction, agglutination of red blood cells in the cold can also lead to cold-induced circulatory symptoms.



DID YOU KNOW?

Avoiding exposure to the cold isn't always enough to avoid hemolysis from occurring.



JoAnn, a patient on ENJAYMO

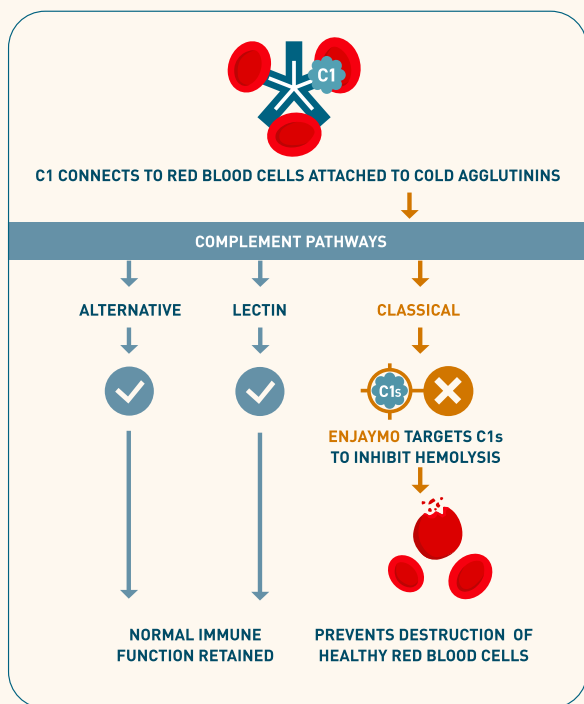
IMPORTANT SAFETY INFORMATION (continued)

- If you have CAD and you stop receiving ENJAYMO, your healthcare provider should monitor you closely for return of your symptoms after you stop ENJAYMO. Stopping ENJAYMO may cause the breakdown of your red blood cells due to CAD to return. Symptoms or problems that can happen due to red blood cell breakdown include: tiredness, shortness of breath, rapid heart rate, and blood in your urine or dark urine.

Please see Important Safety Information throughout and full [Prescribing Information](#) and [Medication Guide](#).



Lonnie, a patient on ENJAYMO



- ENJAYMO is **designed to help inhibit hemolysis**—the destruction of red blood cells—before it starts
- It does this by selectively **targeting and binding to the C1s** protein, a key protein in the classical complement pathway
- The **classical complement pathway** is responsible for hemolysis in Cold Agglutinin Disease
- By binding to the C1s protein, ENJAYMO blocks the classical complement pathway and helps inhibit the chain reaction at the very beginning, **reducing the destruction and removal of healthy red blood cells** by the immune system
- While it inhibits the classical complement pathway, **ENJAYMO leaves the other complement pathways (lectin and alternative pathways)** alone to carry out their immune functions

ENJAYMO does not affect the immune functions of the lectin and alternative pathways.

IMPORTANT SAFETY INFORMATION (continued)

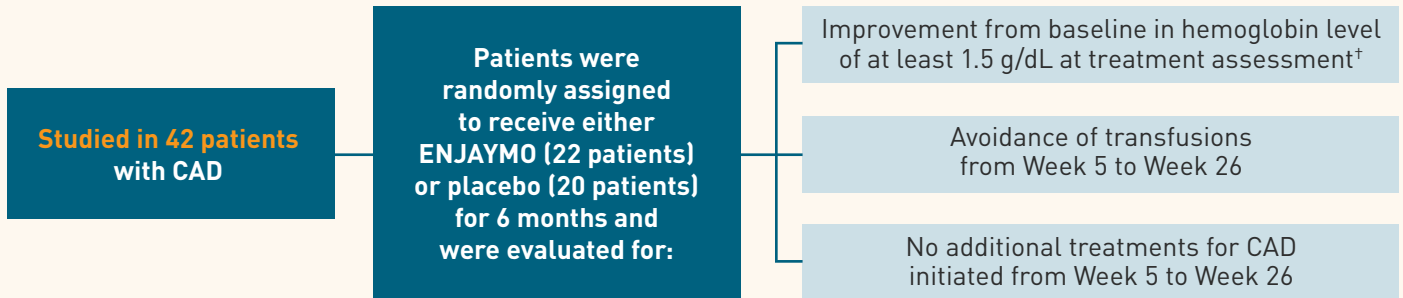
The most common side effects of ENJAYMO include: increase in blood pressure, urinary tract infection, respiratory tract infection, bacterial infection, swelling in lower legs or hands, joint pain, headache, nausea, runny nose, bluish color to the lips and skin, dizziness, feeling tired or weak, cough, and changes in color or sensation in the fingers and toes (Raynaud’s phenomenon).

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JoAnn, a patient on ENJAYMO


ENJAYMO is an FDA-designated breakthrough, chemotherapy-free treatment that helps to address the impact of hemolysis in Cold Agglutinin Disease (CAD)

The safety and efficacy of ENJAYMO were evaluated in two clinical trials. One clinical trial was a placebo-controlled* clinical trial in 42 patients with CAD who did not have a history of blood transfusion in the last 6 months.




The study also looked at symptoms of CAD, hemoglobin and laboratory measures of hemolysis over time.

73% (16/22) of patients responded to treatment with ENJAYMO vs 15% (3/20) on placebo




73% HAD IMPROVED HEMOGLOBIN

73% (16/22) of patients taking ENJAYMO (vs 15.0% [3/20] of patients taking placebo) showed an increase in hemoglobin of at least 1.5 g/dL.



82% REMAINED TRANSFUSION FREE

82% (18/22) of patients taking ENJAYMO (vs 80.0% [16/20] of patients taking placebo) did not receive a blood transfusion from Week 5 through Week 26.



86% DID NOT NEED OTHER MEDICATIONS FOR CAD

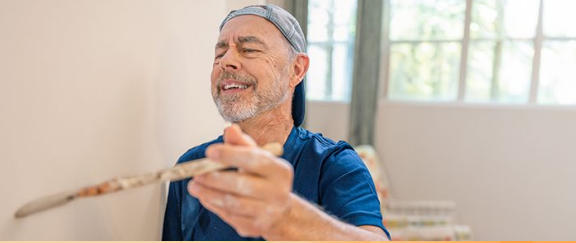
86% (19/22) of patients taking ENJAYMO (vs 100% [20/20] of patients taking placebo) did not receive treatment beyond what was permitted per protocol of the study from Week 5 through Week 26.

*Placebo=a harmless medicine with no therapeutic effect, used as a control in testing new drugs.
 †Defined as the average value from Weeks 23, 25, and 26.

IMPORTANT SAFETY INFORMATION (continued)

These are not all the possible side effects of ENJAYMO. Call your doctor for medical advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please see Important Safety Information throughout and full [Prescribing Information](#) and [Medication Guide](#).



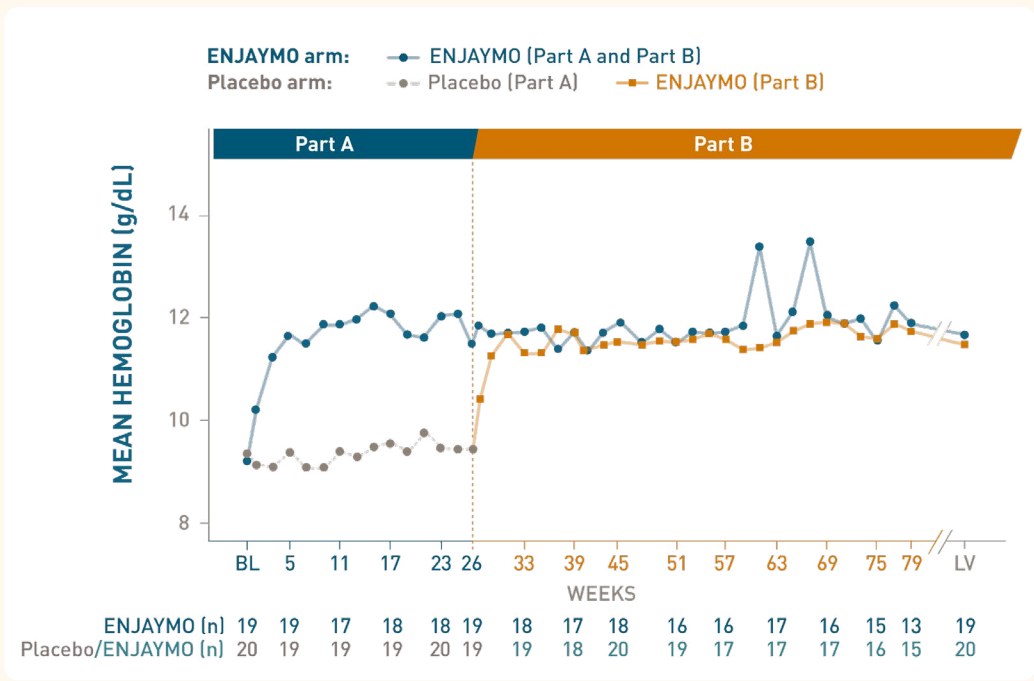
Lonnie, a patient on ENJAYMO

ENJAYMO offered fast and lasting improvement of hemoglobin levels during the study*

In Part A: patients received either ENJAYMO or placebo for 26 weeks (6 months).

In Part B: the placebo patients were switched to ENJAYMO from Week 27 up to one year, and all patients continued on ENJAYMO until the end of the trial.

This graph shows the average change in hemoglobin levels from the start of the study to the end of the study.



Average increase
in hemoglobin
2.0 g/dL
AT WEEK 3

2.66 g/dL
BY WEEK 26

(n)=number of patients tested on ENJAYMO, and placebo/ENJAYMO.

- ▶▶ The blue line shows the change in hemoglobin for people who received ENJAYMO in parts A and B.
- ▶▶ The gray line shows the change in hemoglobin for those who received placebo in part A.
- ▶▶ The orange line shows the change in hemoglobin for those who received placebo in part A and switched to ENJAYMO in part B.
- ▶▶ **Please consider these results with caution as there are certain limitations including a small sample size and only the average values from Weeks 23, 25, and 26 were tested to establish a definite cause and effect relationship.**

The average hemoglobin level at the start of the study was 9.15 g/dL for patients on ENJAYMO and 9.33 g/dL for patients on placebo.

*This was a 26-week randomized, placebo-controlled, Phase 3 trial where 22 patients diagnosed with Cold Agglutinin Disease received ENJAYMO and 20 patients received placebo. The primary endpoint was hemoglobin increase, transfusion independence, and use of other Cold Agglutinin Disease treatment. 39 patients continued to receive ENJAYMO in a long-term safety and durability of response extension phase (part B).

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Nancy, a patient on ENJAYMO

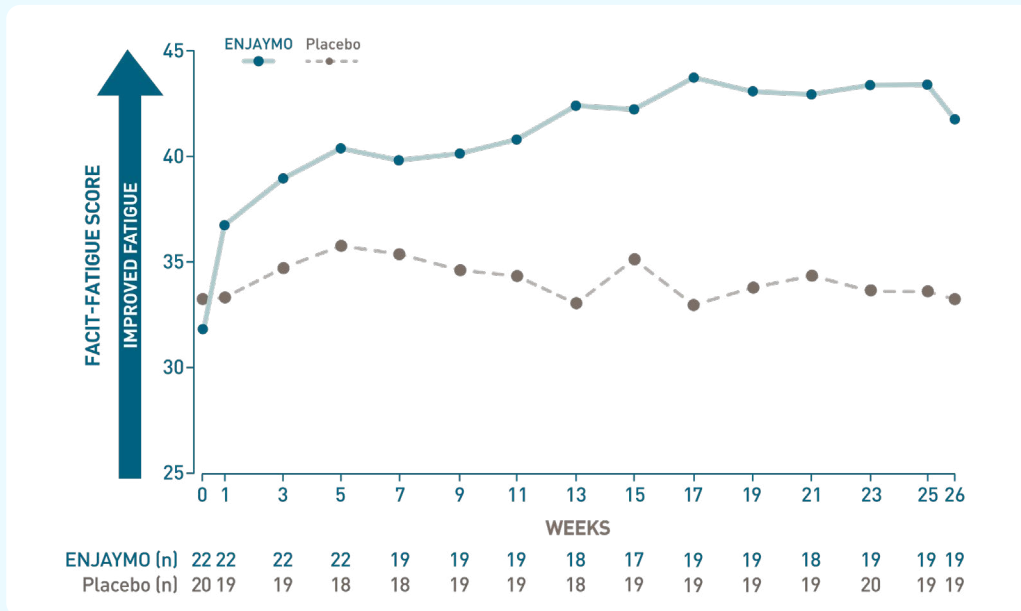
There was also significant improvement in fatigue reported

FACIT-Fatigue is measured on a scale of 0 (most fatigue) to 52 (no fatigue). The higher the score, the less fatigue the patient experienced.

In the clinical trial, patients on ENJAYMO had an average 11-point improvement from baseline (improving from an average baseline score of 31.67 points to an average score at treatment assessment of 42.5 points) vs a 2-point improvement in patients on placebo. Higher scores on the survey meant a person felt less fatigue.

Impact on fatigue as measured by FACIT-Fatigue survey

Patients received either ENJAYMO or placebo for 26 weeks.



Part A: by Week 26

11-POINT
improvement from
baseline in patients
on ENJAYMO
vs a

2-POINT
improvement in
patients on placebo

(n)=number of patients tested on ENJAYMO, and placebo/ENJAYMO.

- ▶▶ The blue line shows the impact on fatigue for people who received ENJAYMO.
- ▶▶ The gray line shows impact on fatigue for those who received placebo in part A.
- ▶▶ Please consider these results with caution as there are certain limitations including a small sample size and only the average values from Weeks 23, 25, and 26 were tested to establish a definite cause and effect relationship.

Please see Important Safety Information throughout and full [Prescribing Information](#) and [Medication Guide](#).



JoAnn, a patient on ENJAYMO

What is the most important information I should know about ENJAYMO?

- ▶▶ ENJAYMO is a medicine that affects your immune system
- ▶▶ ENJAYMO may lower the ability of your immune system to fight infections
- ▶▶ ENJAYMO increases your chance of getting serious infections, including those caused by encapsulated bacteria

- You must complete or be up to date with the vaccines against *Streptococcus pneumoniae* and *Neisseria meningitidis* at least 2 weeks before your first dose of ENJAYMO.
- If your healthcare provider decides that urgent treatment with ENJAYMO is needed, you should receive vaccinations as soon as possible.
- If you have been vaccinated against these bacteria in the past, you might need additional vaccines before starting ENJAYMO. Your healthcare provider will decide if you need additional vaccines.
- Vaccines do not prevent all infections caused by encapsulated bacteria. **Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a serious infection:**
 - fever with or without shivers or chills
 - fever with chest pain and cough
 - fever with high heart rate
 - headache and fever
 - confusion
 - clammy skin
 - fever and a rash
 - fever with breathlessness or fast breathing
 - headache with nausea or vomiting
 - headache with stiff neck or stiff back
 - body aches with flu-like symptoms
 - eyes sensitive to light

- ▶▶ ENJAYMO can cause serious side effects, including infusion-related reactions and risk of autoimmune disease

The most common side effects of ENJAYMO include:

- increase in blood pressure
- urinary tract infection
- respiratory tract infection
- bacterial infection
- swelling in lower legs or hands
- joint pain
- headache
- nausea
- runny nose
- bluish color to the lips and skin
- dizziness
- feeling tired or weak
- cough
- changes in color or sensation in the fingers and toes (Raynaud's phenomenon)

These are not all the possible side effects of ENJAYMO.

You should tell your doctor about any side effect that bothers you or does not go away. There are other possible side effects of ENJAYMO. For more information, ask your doctor or pharmacist.

IMPORTANT SAFETY INFORMATION (continued)

Before receiving ENJAYMO, tell your healthcare provider about all of your medical conditions, including if you: have a fever or infection, including a history of human immunodeficiency virus (HIV), hepatitis B, or hepatitis C; have an autoimmune disease such as systemic lupus erythematosus, also known as lupus; are pregnant or plan to become pregnant. It is not known if ENJAYMO will harm your unborn baby; are breastfeeding or plan to breastfeed. It is not known if ENJAYMO passes into your breast milk.

Please see Important Safety Information throughout and full [Prescribing Information](#) and [Medication Guide](#).



JoAnn, a patient on **ENJAYMO**

What were the possible side effects of ENJAYMO?

Safety was evaluated in two Phase 3 clinical trials

In **CADENZA (Part A)**, participants with Cold Agglutinin Disease with no history of blood transfusion during the 6 months prior to starting the study were randomly selected to receive either ENJAYMO (n=22) or placebo (n=20), and neither they nor their doctor knew which one they were given (double-blind).

- ▮▮ **Serious adverse reactions** occurred in 2/22 (9%) patients who received ENJAYMO. Serious adverse reactions included Raynaud's phenomenon (n=1) and febrile infection (n=1)
- ▮▮ **Permanent discontinuation** of ENJAYMO due to an adverse reaction occurred in 2/22 (9%) patients. Adverse reactions which resulted in permanent discontinuation of ENJAYMO included Raynaud's phenomenon (n=1), acrocyanosis (n=1), and infusion-related reactions (n=1)

In **CARDINAL**, 24 participants with Cold Agglutinin Disease with at least 1 blood transfusion during the 6 months prior to starting treatment received ENJAYMO—and were told what drug they were given (single-arm).

- ▮▮ **Serious adverse reactions** occurred in 10/24 (42%) patients who received ENJAYMO. The most common serious adverse reaction (>5%) was bluish color to the lips and skin. One person who received ENJAYMO died from a bacterial infection reaction
- ▮▮ **Permanent discontinuation** of ENJAYMO due to an adverse reaction occurred in 2/24 (8%) patients. Adverse reactions which resulted in permanent discontinuation of ENJAYMO included *pneumonia klebsiella* (n=1) and acrocyanosis (n=2)

[Click here](#) to learn more about the most common side effects of both clinical trials.

IMPORTANT SAFETY INFORMATION (continued)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Please see Important Safety Information throughout and full [Prescribing Information](#) and [Medication Guide](#).

Lynn, a patient on **ENJAYMO**



See if you can hit RESUME with a focused treatment schedule

The ENJAYMO dosing schedule is designed to provide a continuous level of medicine. ENJAYMO is given as an intravenous (IV) infusion weekly for the first 2 weeks, and then administered every 2 weeks thereafter. Your dose of ENJAYMO (either 6.5 g or 7.5 g) is based on your body weight, which your doctor will determine for you.



Your treatment and what to expect

The infusion process can vary depending on individual needs, but here's an example of what you may expect. Be sure to speak with your healthcare provider with any questions you may have.

▶▶ Before your first infusion

- Talk to your doctor about any medical conditions, your medications, and any tests or vaccinations you'll require before and while on treatment

▶▶ What to expect during your first infusion—and future visits

- On the day of your infusion, a member of your treatment team will bring your ENJAYMO to room temperature
- A healthcare provider will administer ENJAYMO through a vein by intravenous infusion. The process will last between 1 to 2 hours
- After your infusion, you'll be monitored for infusion and allergic reactions by your treatment team for at least 2 hours on your first visit, and for at least 1 hour after all future infusions

▶▶ Stick to your treatment plan

- Arrive for your infusion on time and do not miss an appointment. If more than 17 days pass between ENJAYMO infusions, you will need to receive ENJAYMO weekly for 2 weeks before returning to an infusion schedule of every 2 weeks thereafter
- If you miss an ENJAYMO infusion, call your doctor right away

▶▶ Infusion tips and tricks

Treatment time can vary slightly from patient to patient, but your infusion session will typically last from 1 to 2 hours, plus additional time for your healthcare team to monitor you following your infusion.



DID YOU KNOW?

When considering treatment with ENJAYMO, home infusions may work better for you and your family, and may be possible for you at no cost. Talk to your doctor to see if home infusions may be right for you.

[Click here](#) for more information.

Please see Important Safety Information throughout and full [Prescribing Information](#) and [Medication Guide](#).



Lonnie, a patient on ENJAYMO

Recordati Rare Diseases Patient Solutions (RRD PS)

RRD PS is in your corner to support you on your treatment journey, with:



Case Managers who are experienced in helping people get started on treatments and provide support with common insurance-related questions.



Therapeutic Education Managers,* or TEMs, who can provide education about ENJAYMO and Cold Agglutinin Disease.

Call **1-833-223-2428**

**Monday through Friday, 8 AM to 8 PM ET
OR**

[Click here to get more information.](#)

RRD Financial Assistance Programs

Eligible patients have two options available to save on ENJAYMO treatment:



1 The RRD ENJAYMO Patient Assistance Program

The ENJAYMO Patient Assistance Program provides support for eligible patients who have limited access to treatment due to insurance issues and other financial challenges.†



2 The RRD ENJAYMO Copay Assistance Program

The ENJAYMO Copay Assistance Program may be able to help eligible patients with treatment costs, including out-of-pocket expenses, such as copayments or coinsurance, for patients with commercial health insurance plans.†

*TEMs are paid to provide educational services on behalf of Recordati Rare Diseases. They do not provide medical advice. You should always talk to your doctor about personal medical questions.

†The RRD ENJAYMO Copay Assistance Program (the "Program") is not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, VA, DoD, TRICARE®, or similar federal or state programs, including any state pharmaceutical assistance programs. The Program is not valid where prohibited by law, and savings may vary depending on patients' out-of-pocket costs and infusion costs. Recordati Rare Diseases reserves the right to modify or terminate the Program at any time without notice. Patients will receive all Program details upon registration.

STAYING CONNECTED IS JUST A CLICK AWAY

EVENTS

Register for upcoming educational events.

Helen, a patient on ENJAYMO

PATIENT VIDEOS

See how ENJAYMO helped real people with Cold Agglutinin Disease hit resume after experiencing fatigue.

Gloria, a patient on ENJAYMO

RESOURCES & SUPPORT

Access valuable information and tools to help you on your treatment journey.

Lonnie, a patient on ENJAYMO

CAD CONNECTION

Sign up to connect one-on-one with another patient receiving ENJAYMO.

Duffy, a patient on ENJAYMO

See if ENJAYMO can help you hit RESUME

Ask your doctor if ENJAYMO is right for you.

Visit [ENJAYMO.com](https://www.enjaymo.com) for more information.