


This is your
**COME BACK
FROM CAD**

and this time you're
back where you belong


Enjaymo[®]
sutimlimab-jome
Injection for intravenous use
100 mg/22 mL

ENJAYMO is the **first and only FDA-approved treatment for people with Cold Agglutinin Disease (CAD)**

INDICATION

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.

Please see Important Safety Information throughout this brochure 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)

IMPORTANT SAFETY INFORMATION

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.

Please see Important Safety Information on pages 15-16 and full [Prescribing Information](#) and [Medication Guide](#).



YOUR COME BACK STARTS HERE

There can be a lot to consider when starting any new treatment

In this section, you'll find information that may interest you, including:

- Study results
- How ENJAYMO works
- Safety considerations
- Information about CAD & ENJAYMO

IMPORTANT SAFETY INFORMATION (continued)

- **Serious Infections (continued):**
 - 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.

Please see Important Safety Information on pages 15-16 and Full [Prescribing Information](#) and [Medication Guide](#).

[Click here](#) to watch **Comeback Stories** from real patients taking ENJAYMO.

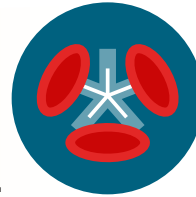
About CAD

What is cold agglutinin disease (CAD)?

CAD is a rare, serious blood disorder and a form of autoimmune hemolytic anemia (AIHA).

When you have CAD, your body makes cold agglutinin antibodies that attach to red blood cells, activating a part of your immune system called the **classical complement pathway**.

When the classical complement pathway is activated, a protein called C1 attaches to your red blood cells, marking them for destruction, a **process known as hemolysis**.



Cold agglutinins mistake red blood cells as a threat, causing hemolysis



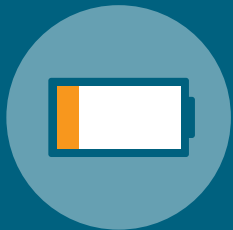
Hemolysis in CAD is triggered by a protein called C1

When red blood cells are destroyed, hemoglobin (a protein that helps to transport oxygen and carbon dioxide throughout the body) is released. Monitoring hemoglobin levels is one way your doctor may keep an eye on hemolysis.

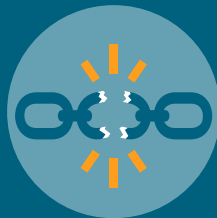
Hemolysis caused by CAD can be an ongoing threat

Symptoms of CAD can be limiting

When the rate of hemolysis is faster than the rate at which the body makes new red blood cells, the result is low levels of red blood cells (anemia). When anemia is ongoing, it can cause you to feel:



Fatigue



Weakness



**Shortness
of Breath**



**Rapid or Irregular
Heart rate**



Chest Pain

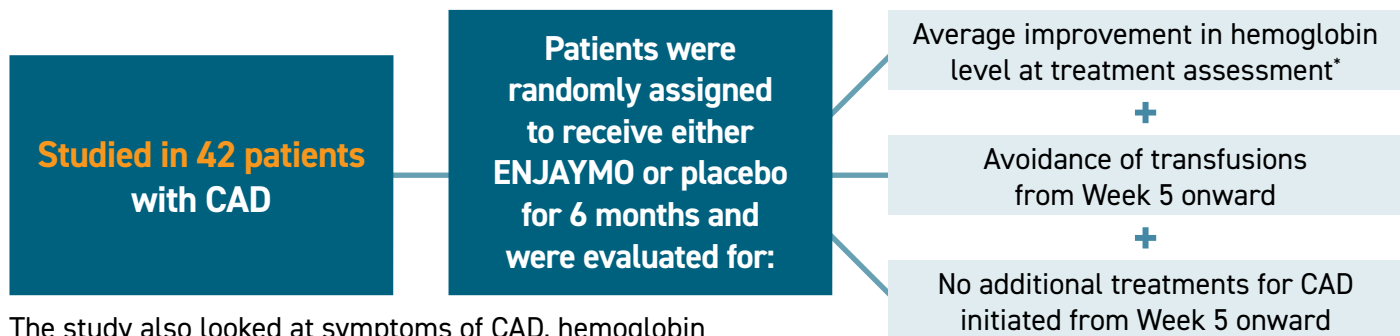


Did you know?

Avoiding exposure to the cold isn't always enough to avoid hemolysis from occurring in patients with CAD.

ENJAYMO Results

ENJAYMO is a breakthrough treatment proven to help address the impact of hemolysis in CAD during a clinical study



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

*Defined as the average value from Weeks 23, 25 and 26.

IMPORTANT SAFETY INFORMATION (continued)

• **Serious Infections (continued):**

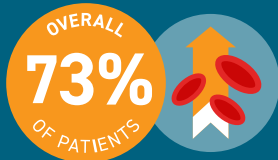
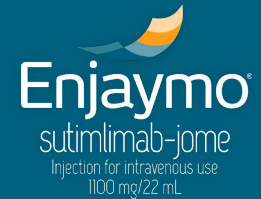
- If you have been vaccinated against these bacteria in the past, you might need additional vaccines before starting ENJAYMO. Your healthcare provider will decide if you need additional vaccines.
- Vaccines do not prevent all infections caused by encapsulated bacteria. Call your healthcare provider or 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

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With ENJAYMO, a comeback from CAD may be possible

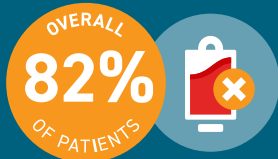
73% (16/22) OF PATIENTS

RESPONDED TO TREATMENT WITH ENJAYMO VS 15% (3/20) ON PLACEBO.
A “RESPONDER” WAS DEFINED AS SOMEONE WHO HAD:



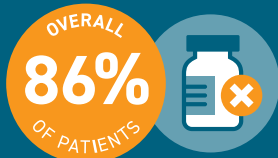
SIGNIFICANT IMPROVEMENT IN HEMOGLOBIN LEVELS

Overall 73% (16/22) of patients on ENJAYMO and 15.0% (3/20) of patients on placebo showed an increase in hemoglobin of at least 1.5 g/dL from baseline.



FREEDOM FROM TRANSFUSIONS

Overall 82% (18/22) of patients on ENJAYMO and 80% (16/20) of patients on placebo did not receive a blood transfusion from Week 5 through Week 26.



NO ADDITIONAL MEDICATIONS FOR CAD

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

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
 - itchy skin

Please see Important Safety Information on pages 15-16 and full [Prescribing Information](#) and [Medication Guide](#).



“Once I started ENJAYMO, it all started to come back. I was no longer tired and fatigued.”

- Duffy, patient taking ENJAYMO

Individual results vary by patient

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
 - unexplained fever

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Significant improvement in fatigue

Patients on ENJAYMO were asked about the impact of fatigue on a scale of 0 (not at all) to 4 (very much so) for a total of 52 points. This 13 item survey (FACIT) included questions like:

- How fatigued they felt
- How weak and tired they felt
- Ability to do usual activities
- Need to take a nap to get through the day
- Frustration because of tiredness

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.

At the end of the study, patients on ENJAYMO had:



Improved hemoglobin levels
vs. patients on placebo



Improvement in self-reported fatigue scores
vs. patients on placebo

IMPORTANT SAFETY INFORMATION (continued)

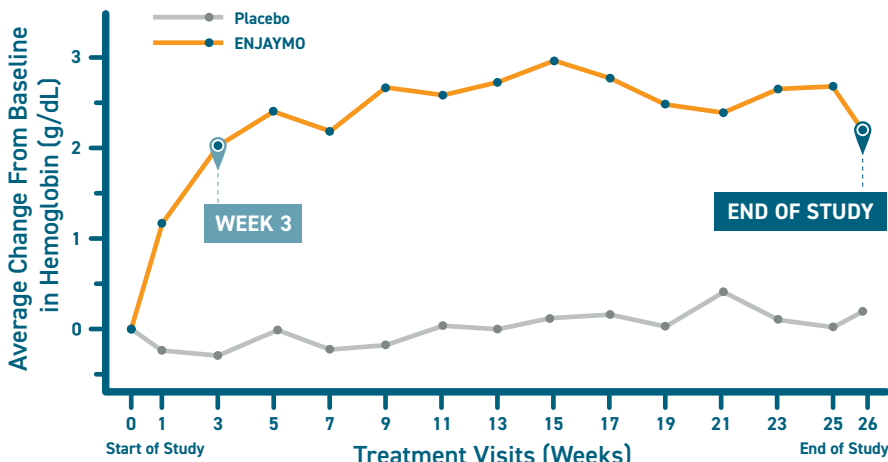
- If you have CAD and you stop receiving ENJAYMO, your healthcare provider should monitor you closely for the return of your symptoms after you stop ENJAYMO. Stopping ENJAYMO may cause the breakdown of your red blood cells due to CAD return. Symptoms or problems that can happen due to red blood cell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

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ENJAYMO offered fast and lasting improvement of hemoglobin levels

In the study, average hemoglobin levels were maintained near normal levels (≥ 12 g/dL) for the duration of treatment

This graph shows the average hemoglobin levels at each time point from the start to the end of the study. Consider that these data come from a small number of patients and that the clinical trial was not designed to determine the statistical significance of these results.



Placebo	20	19	19	19	19	19	19	19	19	19	19	20	19	19
ENJAYMO	22	22	21	22	19	20	17	19	17	18	19	18	19	19

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.



Average Increase in Hemoglobin:

WEEK 3
2.02 g/dL
 (vs 0.31 g/dL placebo)

END*
2.66 g/dL
 (vs 0.09 g/dL placebo)

*Defined as the mean value from Weeks 23, 25 and 26.

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
- changes in color or sensation in the fingers and toes (Raynaud's phenomenon)

These are not all the possible side effects of ENJAYMO. Call your doctor for medical advice about side effects.

Please see Important Safety Information on pages 15-16 and full [Prescribing Information](#) and [Medication Guide](#).

What are the possible side effects of ENJAYMO?

Safety was studied in two phase 3 clinical trials:

In one study, participants with CAD with no history of blood transfusion during the 6 months prior to starting the study were randomized to receive either ENJAYMO (n=22) or placebo (n=20). The study was double-blind, meaning that neither the participants nor the researchers knew whether they were receiving ENJAYMO or placebo.

The most common side effects ($\geq 18\%$) reported in the study were runny nose, headache, high blood pressure, bluish-purple skin discoloration, and decreased blood flow to the fingers and/or toes.

Serious side effects occurred in 2 out of 22 (9%) patients who received ENJAYMO and included decreased blood flow to the fingers and/or toes and infection with fever.

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 (SLE), also known as lupus.

Please see Important Safety Information on pages 15-16 and full [Prescribing Information](#) and [Medication Guide](#).

ENJAYMO has also been studied in 24 participants with CAD with at least 1 blood transfusion during the 6 months prior to starting treatment. The study was single-arm and open-label, meaning that all of the participants received ENJAYMO and they knew what drug they were given.

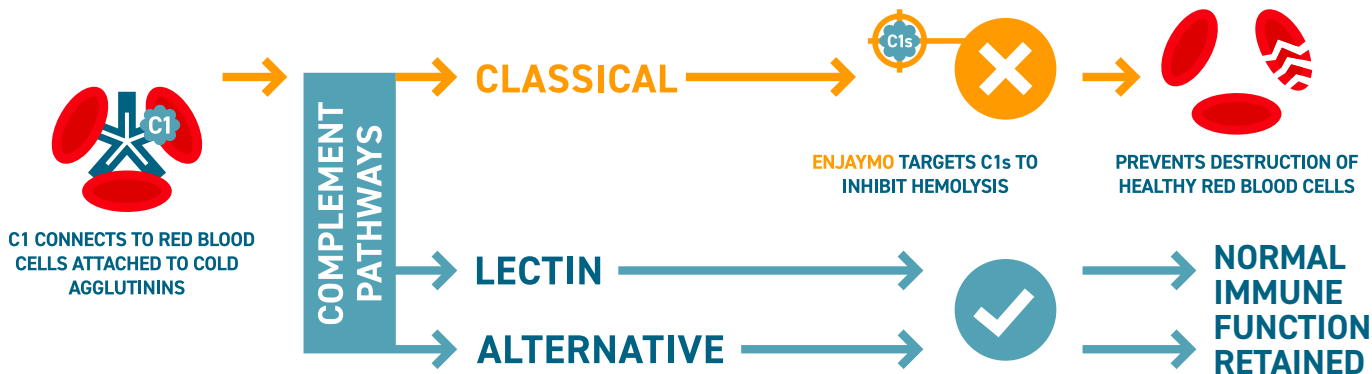
Serious side effects occurred in 10 out of 24 (42%) patients who received ENJAYMO. The most common serious adverse reaction ($>5\%$) was bluish-purple skin discoloration. One person who received ENJAYMO died from a bacterial infection reaction.

The most common side effects ($\geq 25\%$) reported in the study were urinary tract infection, respiratory tract infection, bacterial infection, dizziness, fatigue, swelling in the arms and/or legs, joint pain, cough, high blood pressure, and nausea.

How ENJAYMO Works



ENJAYMO is a treatment option designed to help stop hemolysis before it starts



By binding to C1s, a component of the first protein in the classical complement pathway, ENJAYMO helps stop the chain reaction at the very beginning, preventing your red blood cells from being destroyed.

ENJAYMO can help you take control over chronic hemolysis, so you can call the shots again

IMPORTANT SAFETY INFORMATION (continued)

Before receiving ENJAYMO, tell your healthcare provider about all of your medical conditions, including if you (continued):

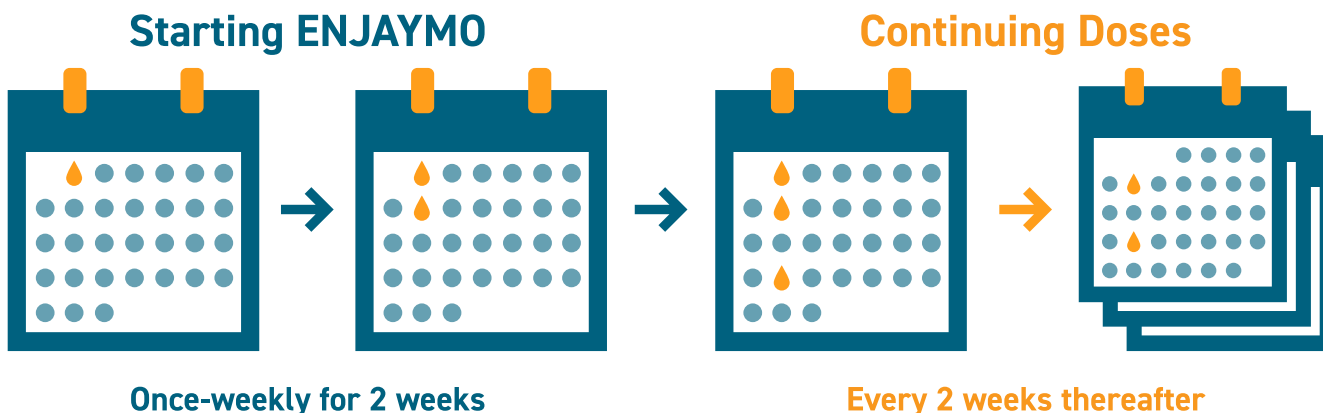
- are pregnant or plan to become pregnant. It is not known if ENJAYMO will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ENJAYMO passes into your breast milk.

Please see Important Safety Information on pages 15-16 and full [Prescribing Information](#) and [Medication Guide](#).

Taking ENJAYMO

A strong game plan can mean a strong comeback

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.



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.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Please see Important Safety Information on pages 15-16 and full [Prescribing Information](#) and [Medication Guide](#).

Get ready to set your course with ENJAYMO

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.



Getting ready for your infusion

- Before using ENJAYMO, you should talk to your doctor about all your medical conditions, the medicines you take, and what tests and vaccinations you require before and while on treatment



What to expect during your infusion

- ENJAYMO is administered by your healthcare professional through a vein by intravenous infusion over 1 to 2 hours
- On the day of infusion, a member of your treatment team will bring your ENJAYMO up to room temperature
- After your infusion, you'll be monitored for allergic reactions by your treatment team for at least 2 hours on your first visit, and for at least 1 hour after future infusions



Make sure you stick to your treatment plan

- Make sure to have your infusion on time and do not miss an appointment. Treatment interruptions may cause the return of symptoms of chronic hemolysis

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.

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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

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.

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 - 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
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 - confusion
 - clammy skin
 - fever and a rash
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 - headache with stiff neck or stiff back
 - body aches with flu-like symptoms
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- **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:
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 - rapid heartbeat
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 - injection site reaction
 - flushing
 - headache
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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
 - unexplained fever
- 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 return. Symptoms or problems that can happen due to red blood cell breakdown include:
 - tiredness
 - shortness of breath
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The most common side effects of ENJAYMO include:

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

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- have an autoimmune disease such as systemic lupus erythematosus (SLE), also known as lupus.
- are pregnant or plan to become pregnant. It is not known if ENJAYMO will harm your unborn baby.
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Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

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“My experience with ENJAYMO has taught me that the smallest little thing can mean amazing things in your life.”

- Helen, patient taking ENJAYMO

Individual results vary by patient

IMPORTANT SAFETY INFORMATION (continued)

• Serious Infections (continued):

- 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.

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SUPPORTING YOUR
COME BACK
EVERY STEP OF THE
WAY

No matter where you are in the process, learn about some of the resources available to provide the support you need when it comes to starting ENJAYMO and continuing with treatment. Have support in your corner with **ENJAYMO Patient Solutions**.

Visit [ENJAYMO.com](https://enjaymo.com) for additional resources including:

IMPORTANT SAFETY INFORMATION (continued)

• **Serious Infections (continued):**

- 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.
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 - fever with breathlessness or fast breathing
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 - headache with stiff neck or stiff back
 - body aches with flu-like symptoms
 - eyes sensitive to light

[Click here](#) to watch **Comeback Stories** from real patients taking ENJAYMO.

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ENJAYMO Patient Solutions

ENJAYMO Patient Solutions is here to help support you through your journey

Meet the team that's ready to support you



Case Managers are experienced in helping people get started on treatment and assisting with insurance-related needs.



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

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 any healthcare needs.

We're available to assist you
Monday through Friday,
8 AM to 8 PM ET,
at **1-833-223-2428**



Financial Assistance Programs for eligible patients

The ENJAYMO Patient Solutions Financial Assistance Programs are designed to provide support for eligible patients who wouldn't be able to access ENJAYMO otherwise. There are two options available:



The Copay Assistance Program

ENJAYMO Copay Assistance Program may be able to help with eligible patients' treatment costs, such as out-of-pocket, co-payments or co-insurance if they meet the program requirements.*



The Patient Assistance Program

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

*The ENJAYMO Patient Solutions Copay 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. 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.

Please see Important Safety Information on pages 15-16 and full [Prescribing Information](#) and [Medication Guide](#).

Talking To Your Doctor

Being prepared with questions can help you get the most out of a conversation with your healthcare provider. Here are some questions you might consider asking:

1. Can ENJAYMO help improve hemoglobin levels and fatigue?

2. How is ENJAYMO administered, and how often?

3. How does ENJAYMO work?

4. What are the most common side effects of ENJAYMO?

5. What should I do if I miss an infusion dose?



**It's time to plan
your comeback**

Visit [ENJAYMO.com](https://www.enjaymo.com)
for information and
resources about
ENJAYMO.

Additional questions for your healthcare provider and other notes



**Please see Important Safety Information on pages 15-16 and full
[Prescribing Information](#) and [Medication Guide](#).**

ENJAYMO is a chemotherapy-free treatment proven to increase hemoglobin by helping to stop hemolysis before it starts



OVERALL
73%
OF PATIENTS

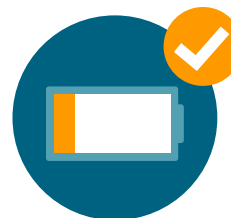
Overall 73% (16/22) of patients had significant increases in hemoglobin levels,* remained transfusion-free,[†] and did not need any other medications for CAD

Improved hemoglobin and symptoms of fatigue

At the end of the study, patients on ENJAYMO had:



Improved hemoglobin levels
vs. patients on placebo



Improvement in self-reported fatigue
scores vs. patients on placebo

* ≥ 1.5 g/dL increase in hemoglobin from the start of treatment

[†]No blood transfusions from Week 5 through Week 26

IMPORTANT SAFETY INFORMATION (continued)

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- rapid heartbeat
- nausea
- injection site reaction
- flushing
- headache
- dizziness
- rash
- itchy skin

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Stay Connected

Patient Portrayal


Enjaymo[™]
sutimlimab-jome
Injection for intravenous use
100 mg/22 mL

YOUR COMEBACK STARTS HERE

Ask your doctor how ENJAYMO could help give you back some control

Learn more information,
visit us at [ENJAYMO.com](https://www.enjaymo.com).

 **RECORDATI
RARE DISEASES**
Focused on the Few[®]

 Find us at [Facebook.com/EnjaymoRx](https://www.facebook.com/EnjaymoRx)

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