

**MEDICATION GUIDE**  
**ENJAYMO® (en-jaye-moe)**  
**(sutimlimab-jome)**  
**injection, for intravenous use**

**Rx Only**

**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**, 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
    - eyes sensitive to light

For more information about side effects, see **“What are the possible side effects of 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.

**Who should not receive ENJAYMO?**

**Do not receive ENJAYMO** if you are allergic to sutimlimab-jome or any of the ingredients in ENJAYMO. See the end of this Medication Guide for a complete list of ingredients in ENJAYMO.

**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.
- 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. You should talk to your healthcare provider about the best way to feed your baby during treatment with ENJAYMO.

**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.

**How will I receive ENJAYMO?**

- ENJAYMO is given through a vein by intravenous (I.V.) infusion, usually over 1 to 2 hours.
- You will usually receive a starting dose of ENJAYMO, followed by a second dose of ENJAYMO 1 week later. Then 2 weeks after your second dose, you will start to receive an ENJAYMO infusion every 2 weeks.
- After your first infusion, you should be monitored for infusion and allergic reactions for at least 2 hours. For all future infusions, you should be monitored for infusion reactions for 1 hour. See **“What are the possible side effects of ENJAYMO?”**
- **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
  - blood in your urine or dark urine
- If you miss an ENJAYMO infusion, call your healthcare provider right away.

**What are the possible side effects of ENJAYMO?**

**ENJAYMO can cause serious side effects, including:**

- See **“What is the most important information I should know about ENJAYMO?”**
- **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

● **Risk of autoimmune disease.** ENJAYMO may increase your risk for developing an autoimmune disease such as 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

**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. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective use of ENJAYMO.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about ENJAYMO that is written for health professionals.

**What are the ingredients in ENJAYMO?**

**Active ingredient:** sutimlimab-jome

**Inactive ingredients:** polysorbate 80, sodium chloride, sodium phosphate dibasic heptahydrate, sodium phosphate monobasic monohydrate, and Water for Injection, USP.

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For more information, go to [www.ENJAYMO.com](http://www.ENJAYMO.com) or call 1-800-745-4447.

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