

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

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

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

**Serious infections.** ENJAYMO is a prescription medicine that affects your immune system. ENJAYMO can lower the ability of your immune system to fight infections. People who take ENJAYMO may have an increased risk of getting infections caused by certain kinds of bacteria such as *Neisseria meningitides*, *Streptococcus pneumoniae*, and *Haemophilus influenzae*. These infections may be serious or life-threatening. Some infections may quickly become life-threatening or cause death if not recognized and treated early.

- You need to receive vaccinations against infections caused by certain kinds of bacteria at least 2 weeks before your first dose of ENJAYMO. You may need to have additional vaccinations during treatment with ENJAYMO.
- If your healthcare provider decides that urgent treatment with ENJAYMO is needed, you should receive vaccinations as soon as possible.
- Vaccinations may reduce the risk of these infections, but do not prevent all infections. **Call your healthcare provider or get medical help right away if you get any new signs and symptoms of an infection, including:**
  - fever
  - severe headache with stiff neck or back
  - pain during urination or urinating more often than usual
  - cough or difficulty breathing
  - flu-like symptoms
  - pain, redness or swelling of the skin

See **"What are the possible side effects of ENJAYMO?"** for more information about side effects.

**What is ENJAYMO?**

ENJAYMO is a prescription medicine used to decrease the need for red blood cell transfusion due to 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 should 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
  - rapid heartbeat
  - nausea
  - flushing
  - headache

- **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:**

- respiratory tract infection
- viral infection
- diarrhea
- indigestion
- cough
- joint pain
- joint inflammation (arthritis)
- swelling of the lower legs, ankles, and feet

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 the 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.

Manufactured by: Bioverativ USA Inc., Waltham, MA 02451. A SANOFI COMPANY. US License No. 2078

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

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