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

PRESCRIBER SAFETY BROCHURE

This guide provides information on important potential risk of serious infections (including meningococcal infections), immunization recommendations, monitoring patients, and counseling patients.

INDICATION

ENJAYMO (sutimlimab-jome) is indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD).

Important potential risk of serious infections including meningococcal infections[1]

ENJAYMO targets the classical complement pathway specifically binding to complement protein component 1, s subcomponent (C1s) preventing the cleavage of complement protein C4; patients may have an increased susceptibility to serious infections, especially infections caused by encapsulated bacteria such as *Neisseria meningitides* (any serogroup), *Streptococcus pneumoniae*, and *Haemophilus influenzae*.

Please see full Prescribing Information.

Immunization recommendations[1]

- Review patients' immunization history
- Patients without a prior history of completed vaccinations (or if the interval from the prior vaccination requires revaccination based on the most current Advisory Committee on Immunization Practices [ACIP]) against encapsulated bacteria, including meningicoccal and streptococcal vaccines, should be vaccinated in accordance with ACIP guidelines for patients with persistent complement deficiency at least 2 weeks prior to receiving the first dose of ENJAYMO
- If urgent ENJAYMO therapy is indicated in an unvaccinated patient, administer vaccine(s) as soon as possible
- Vaccination reduces, but does not eliminate, the risk of encapsulated bacterial infections

Monitoring patients[1]

- Monitor patients for early signs and symptoms of infections and evaluate patients immediately if infection is suspected
- If ENJAYMO treatment is administered to patients with active systemic infections, monitor closely for signs and symptoms of worsening infection. ENJAYMO has not been studied in patients with chronic systemic infections such as hepatitis B, hepatitis C, or HIV. Consider patients' immune status when initiating treatment with ENJAYMO

Patient counseling[1]

- Tell your patients about the potential risk of infections, including meningococcal infections, and counsel them to read the medication guide carefully
- Inform patients that they are required to receive vaccinations according to current medical guidelines prior to initiation of and during treatment with ENJAYMO
- Instruct your patients to seek immediate medical attention if they suspect they may have an infection or develop any of the following symptoms:
  - Shortness of breath
  - Rapid heartbeat
  - Nausea
  - Flushing
  - Headache
  - Fatigue
  - Dyspnea
  - Palpitations
  - Hemoglobinuria

Reporting suspected adverse reactions after authorization of the medicinal product is important.

It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions.

Adverse events should be reported to a Sanofi Medical Information Healthcare Professional at 800-633-1610. Select Option 1.

For more information about ENJAYMO, please visit ENJAYMOhcp.com

This brochure does not provide all risk information for ENJAYMO.

Please see full Prescribing Information for ENJAYMO and Medication Guide for more detailed safety information.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Serious Infections

- ENJAYMO may increase susceptibility to serious infections, including infections caused by encapsulated bacteria such as *Neisseria meningitides* (any serogroup), *Streptococcus pneumoniae*, and *Haemophilus influenzae*.
- Serious infections (bacterial and viral) were reported in 17% (4/24) of patients receiving ENJAYMO in a single-arm open-label clinical trial.
- Vaccinate patients for encapsulated bacteria according to the most current ACIP recommendations for patients with persistent complement deficiencies. Revaccinate patients in accordance with ACIP recommendations.
- Immunize patients without a history of vaccination against encapsulated bacteria at least 2 weeks prior to receiving the first dose of ENJAYMO. If urgent ENJAYMO therapy is indicated in an unvaccinated patient, administer vaccine(s) as soon as possible.
- If ENJAYMO treatment is administered to patients with active systemic infections, monitor closely for signs and symptoms of worsening infection. Some infections may become rapidly lifethreatening or fatal if not recognized and treated promptly. Inform patients of these signs and symptoms and steps to be taken to seek immediate medical care.
  - Consider interruption of ENJAYMO treatment in patients who are undergoing treatment for serious infection.
  - Consider patients' immune status when initiating treatment with ENJAYMO.

Infusion-Related Reactions

- Administration of ENJAYMO may result in infusion-related reactions. In the CARDINAL study, 8% (2/24) of patients treated with ENJAYMO experienced infusion-related reactions.
- 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.
- Monitor patients being treated with ENJAYMO 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, e.g., 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 (≥10%) with ENJAYMO were respiratory tract infection, viral infection, diarrhea, dyspepsia, cough, arthralgia, arthritis, and peripheral edema.

Please see full Prescribing Information.

For more information, visit ENJAYMOhcp.com

Reference: 1. ENJAYMO. Prescribing information. Genzyme Corporation.

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