ENJAYMO™ (sutimlimab)

PHYSICIAN'S GUIDE

- This guide provides information on:
  - Indication
  - Risk of serious infections and meningococcal infections.
  - Patient vaccination recommendations
  - Monitoring patients
  - Counseling patients

Version 04/2025

Indication[1]

ENJAYMO (sutimlimab) is indicated for treatment of haemolytic anaemia in adult patients with cold agglutinin disease

Risk of serious infections and meningococcal infections[1]

ENJAYMO (sutimlimab) targets the classical complement pathway, specifically binding to complement protein component 1, s subcomponent (C1s), preventing the cleavage of complement protein C4. Although the lectin and alternate pathways remain unaffected, patients may have an increased susceptibility to serious infections, especially infections caused by encapsulated bacteria such as *Neisseria meningitides*, *Streptococcus pneumoniae*, and *Haemophilus influenza*

ENJAYMO (sutimlimab) should not be initiated in patients with active, serious infections.

Immunization[1]

- Patients should be vaccinated against encapsulated bacteria before treatment with ENJAYMO (sutimlimab) is started
- Vaccinate patients according to the current local recommendations for patients with persistent complement deficiencies, including meningococcal (meningococcal conjugate and meningococcal serogroup B) and pneumococcal vaccines
- Vaccination reduces but does not eliminate the risk of infections
- Immunize patients without a history of vaccination against encapsulated bacteria at least 2 weeks prior to receiving the first dose of ENJAYMO (sutimlimab)
- If urgent ENJAYMO (sutimlimab) therapy is needed in an unvaccinated patient, administer vaccine(s) as soon as possible
- Patients treated with ENJAYMO (sutimlimab) should receive booster doses of vaccines in accordance with local recommendations
- The benefits and risks of antibiotic prophylaxis for prevention of infections in patients receiving ENJAYMO (sutimlimab) have not been established

Monitoring patients[1]

- Monitor patients closely for early signs and symptoms of infections such as meningitis, sepsis, and pneumonia, evaluate immediately if infection is suspected, and treat as appropriate
- If ENJAYMO (sutimlimab) treatment is administered to patients with active systemic infections, monitor closely for signs and symptoms of worsening infection. Use with caution when treating patients with serious infections, chronic systemic infections (such as hepatitis B or C or HIV), or those who may be immunocompromised

Patient counselling[1,2]

- Tell your patients about the risk of serious infections and meningococcal infections, and counsel them to read both the patient leaflet and patient's guide carefully
- Instruct your patients to seek medical attention as soon as possible if they suspect they may have an infection or develop any of the following symptoms:
    - Fever with or without rash
    - Chills
    - Flu-like symptoms
    - Cough/difficulty breathing
    - Headache with nausea, vomiting, stiff neck, stiff back
    - Confusion
    - Eye sensitivity to light
    - Pain during urination or urinating more often

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 via the national reporting system:

Lægemiddelstyrelsen
Axel Heides Gade 1
DK-2300 København S
Websted: www.meldenbivirkning.dk

For more information about ENJAYMO (sutimlimab), please contact

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REFERENCE:

1. ENJAYMO summary of product characteristics
2. ENJAYMO package leaflet

www.ema.europa.eu Enjaymo | European Medicines Agency (EMA)

Dette dokument blev senest godkendt af Lægemiddelstyrelsen i 11 apr 2025

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