



NOW APPROVED

for adults with moderately to severely active Crohn's disease

SPEAKERS



**Dr. Jessica
Allegretti, MD**



**Dr. David
Rubin, MD**

The program will discuss the role of inflammation in Crohn's disease, relevant clinical data, and the importance of various clinical outcomes.

**Monday, May 5
12:15 PM–1:00 PM
DDW Theater 1
in the Exhibit Hall**

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INDICATION

TREMFYA® is indicated for the treatment of adult patients with moderately to severely active Crohn's disease.

IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

TREMFYA® is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarket use of TREMFYA®. Some cases required hospitalization. If a serious hypersensitivity reaction occurs, discontinue TREMFYA® and initiate appropriate therapy.

Infections

TREMFYA® may increase the risk of infection. Treatment with TREMFYA® should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

Consider the risks and benefits of treatment prior to prescribing TREMFYA® in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving TREMFYA® to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient

develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and discontinue TREMFYA® until the infection resolves.

Tuberculosis (TB)

Evaluate patients for TB infection prior to initiating TREMFYA® treatment. Do not administer TREMFYA® to patients with active TB infection. Initiate treatment of latent TB prior to administering TREMFYA®. Consider anti-TB therapy prior to initiating TREMFYA® in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor all patients for signs and symptoms of active TB during and after TREMFYA® treatment.

Hepatotoxicity

A serious adverse reaction of drug-induced liver injury was reported in a clinical trial subject with Crohn's disease following three doses of a higher than recommended induction regimen.

In patients with Crohn's disease or ulcerative colitis, evaluate liver enzymes and bilirubin at baseline, for at least 16 weeks of treatment, and periodically thereafter according to routine patient management.

Consider other treatment options in patients with evidence of acute liver disease or cirrhosis. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. Interrupt treatment if drug-induced

liver injury is suspected, until this diagnosis is excluded. Instruct patients to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction.

Immunizations

Prior to initiating TREMFYA®, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines in patients treated with TREMFYA®.

ADVERSE REACTIONS

Most common adverse reactions associated with TREMFYA® include: ulcerative colitis adverse reactions (≥2%): induction: respiratory tract infections; maintenance (≥3%): injection site reactions, arthralgia, and upper respiratory tract infections. Crohn's disease adverse reactions (≥3%): respiratory tract infections, abdominal pain, injection site reactions, headache, fatigue, arthralgia, diarrhea, and gastroenteritis.

Please see accompanying full Prescribing Information and Medication Guide for TREMFYA® in holder. Provide the Medication Guide to your patients and encourage discussion.

Dosage Forms and Strengths: TREMFYA® is available as 100 mg/mL and 200 mg/2 mL for subcutaneous injection and as a 200 mg/20 mL (10 mg/mL) single-dose vial for intravenous infusion.

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