Generic Name:
Tofacitinib
Trade Name:
Xeljanz
Company:
Pfizer
Notes:

FDA expanded the approval of tofacitinib to include adults with moderately to severely active ulcerative colitis.

It is the first oral medication approved for chronic use in this indication. Other FDA-approved treatments for chronic treatment of this condition must be administered through an I.V. infusion or S.C. injection.

Efficacy of tofacitinib for treatment of moderately to severely active ulcerative colitis was demonstrated in three controlled clinical trials. This included two 8-week placebo-controlled trials that demonstrated that 10 mg of tofacitinib given twice daily induces remission in 17% to 18% of patients by week eight.

In a placebo-controlled trial among patients who achieved a clinical response by week eight, a 5- or 10-mg dose of tofacitinib given twice daily was effective in inducing remission by week 52 in 34% and 41% of patients, respectively. Among patients who achieved remission after 8 weeks of treatment, 35% and 47% achieved sustained corticosteroid-free remission when treated with 5 mg and 10 mg, respectively.

Safety of chronic use of tofacitinib for ulcerative colitis was studied in the 52-week placebo-controlled trial. Additional supportive safety information was collected from patients who received treatment in an open-label, long-term study.

The most common adverse events associated with treatment for ulcerative colitis were diarrhea, elevated cholesterol levels, headache, increased blood creatine phosphokinase, common cold, rash, and upper respiratory tract infection.

Less common serious adverse events included malignancy and serious infections such as opportunistic infections. Tofacitinib has a boxed warning for serious infections and malignancy. Patients treated with tofacitinib are at increased risk for developing serious infections that may lead to hospitalization or death. Lymphoma and other malignancies have been observed in patients treated with tofacitinib.

Use of tofacitinib in combination with biological therapies for ulcerative colitis or with potent immunosuppressants, such as azathioprine and cyclosporine, is not recommended.

The agent was previously approved in 2012 for rheumatoid arthritis and in 2017 for psoriatic arthritis.

Medication Monitor Categories:
Supplemental Approvals