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

FDA and Pfizer announced the approval of tofacitinib, a Janus kinase (JAK) selective inhibitor, to treat adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. Tofacitinib is designed to inhibit the JAK pathways, which are signaling pathways inside the cell that play an important role in the inflammation involved in RA.

Tofacitinib is indicated to be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs), and it should not be used in combination with biologic DMARDs or potent immunosuppressives, such as azathioprine and cyclosporine. The recommended dose of tofacitinib is 5 mg, taken orally, twice daily. FDA noted that this new drug is being approved 2 weeks ahead of the scheduled product?s prescription drug user fee goal date of November 21, 2012.

Approval was based on data from seven clinical trials in adult patients with moderately to severely active RA. In all of the trials, patients treated with tofacitinib experienced improvement in clinical response and physical functioning compared with patients treated with placebo. The most commonly reported adverse events were upper respiratory tract infections, headache, diarrhea, and nasopharyngitis. In addition, the drug has also been associated with serious adverse events such as infections, including tuberculosis and herpes zoster; malignancies, including lymphoma; gastrointestinal perforations; decreased neutrophil and lymphocyte counts; decreased hemoglobin; liver enzyme elevations; and lipid elevations. Tofacitinib has a boxed warning describing some of these serious risks.

FDA noted that tofacitinib was approved with a Risk Evaluation and Mitigation Strategy (REMS) which includes a Medication Guide for patients, a communication plan for health care providers and pharmacists, and periodic REMS assessment submissions. In addition, Pfizer has agreed to conduct postmarketing clinical trials to evaluate the long-term safety of tofacitinib in the pediatric population with polyarticular juvenile ideopathic arthritis.

**Medication Monitor Categories:**
New Drug Approvals
**Use:**

Second-line agent for moderately to severely active RA

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