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

FDA is alerting the public that a safety clinical trial found an increased risk of blood clots in the lungs and death when a 10-mg twice-daily dose of tofacitinib was used in patients with rheumatoid arthritis (RA). FDA has not approved this 10-mg twice-daily dose for RA; this dose is only approved in the dosing regimen for patients with ulcerative colitis.

In this ongoing safety trial required by FDA when it approved tofacitinib for RA, the drug manufacturer, Pfizer, is transitioning patients who were on the high 10-mg twice-daily dose to the lower, currently approved dose of 5 mg twice daily. This trial will continue and is expected to be completed by the end of 2019. FDA said it is working with the manufacturer to evaluate other currently available safety information for tofacitinib and will update the public with any new information based on its ongoing review.

Health care professionals should follow the recommendations in the tofacitinib prescribing information for the specific condition they are treating. Monitor patients for the signs and symptoms of pulmonary embolism, and advise them to seek medical attention immediately if they experience them.

Patients should not stop or change their dose of tofacitinib without first talking to their health care provider, as doing so may worsen their condition. Patients taking tofacitinib should seek medical attention immediately if they experience symptoms of a blood clot in their lungs or other unusual symptoms, such as sudden shortness of breath or difficulty breathing, chest pain or pain in your back, coughing up blood, excessive sweating, or clammy or bluish colored skin.

Tofacitinib was first approved in 2012 to treat adult patients with RA who did not respond well to the medicine methotrexate. In 2018, FDA approved tofacitinib to treat ulcerative colitis.

Medication Monitor Categories:
Alerts and Recalls