FDA: blood clot, death risk up with higher dose of tofacitinib

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New warnings about an increased risk of thrombosis and of death among ulcerative colitis patients taking the 10 mg twice daily dose of the drug tofacitinib (Xeljanz, Xeljanz XR) have been issued by the U.S. Food and Drug Administration.

The agency also said that the approved use of tofacitinib for ulcerative colitis will be restricted to certain patients who do not respond to, or who have severe side effects with, certain other medicines.

The changes, including adding the FDA's most prominent Boxed Warning, were made after the agency reviewed interim data from an ongoing clinical trial assessing the safety of 5 mg and 10 mg twice daily doses of tofacitinib in patients with rheumatoid arthritis. That data showed an increased risk of blood clots and of death in patients treated with the 10 mg twice daily dose, compared with tofacitinib 5 mg twice daily or a tumor necrosis factor blocker, according to the FDA. The agency first approved tofacitinib in 2012 to treat adult patients with rheumatoid arthritis who did not respond well to methotrexate. The approved dose for those patients is 5 mg twice a day. In 2018, the FDA approved the drug to treat ulcerative colitis.

The FDA said health care professionals should counsel patients to stop taking tofacitinib and seek immediate emergency medical attention if they develop any unusual symptoms, including those that may signal a blood clot. Health care providers should avoid prescribing tofacitinib for patients who may have a higher risk of thrombosis, and use tofacitinib at the lowest effective dose or limit the duration of the 10 mg twice daily dosage when treating ulcerative colitis.

More information: More Information