Immediate Release: New Boxed Warning on Xeljanz and Xeljanz XR (tofacitinib)

On July 26, 2019, the U.S. Food and Drug Administration (FDA) made a drug safety announcement regarding new approvals and changes to the product labeling for tofacitinib (Xeljanz and Xeljanz XR). The FDA approved the addition of new warnings and a Boxed Warning regarding an increased risk of blood clots and death associated with the 10 mg twice-daily dose. Also, while tofacitinib has been approved to treat ulcerative colitis since 2018, the FDA decided to limit its use to ulcerative colitis patients who are not being effectively treated or who are experiencing severe side effects with certain other medications, such as tumor necrosis factor (TNF) inhibitors.

Xeljanz and Xeljanz XR work by decreasing immune system activity and are indicated to treat rheumatoid arthritis, psoriatic arthritis and ulcerative colitis. When tofacitinib was first approved in 2012, the FDA required a post-market clinical study analyzing the risk of cardiac events, cancer and infections in patients with rheumatoid arthritis taking methotrexate. Patients were given either 5 mg or 10 mg of tofacitinib twice daily or a TNF inhibitor. During the study, investigators found that patients receiving tofacitinib 10 mg twice daily had an increased occurrence of blood clots and death compared to those receiving the 5 mg twice-daily dose or the TNF inhibitor.

Patients with a history of blood clots or heart problems are advised to talk with their healthcare providers about any questions or concerns. Patients should stop taking tofacitinib and seek emergency medication attention immediately if they experience any unusual symptoms, such as sudden shortness of breath, chest pain that worsens with breathing, leg pain or tenderness, or swelling or discoloration of extremities, as these may be signs of a blood clot.

Healthcare providers should not prescribe tofacitinib for patients at high-risk for blood clots, and it should be discontinued if a patient experiences symptoms suggesting blood clots. When used to treat ulcerative colitis, the lowest effective dose is recommended and the 10 mg twice-daily dose should be limited to the shortest duration necessary.

For additional information view the FDA's Drug Safety Communication or MedWatch.

References

1. Xeljanz, Xeljanz XR (tofacitinib): Drug Safety Communication - Due to an Increased Risk of Blood Clots and Death with Higher Dose. U.S. Food & Drug Administration. https://www.fda.gov/safety/medical-product-safety-information/xeljanz-xeljanz-xr-tofacitinib-drug-safety-communication-due-increased-risk-blood-clots-and-death. Updated July 26, 2019. Accessed September 9, 2019.
2. FDA approves Boxed Warning about increased risk of blood clots and death with higher dose of arthritis and ulcerative colitis medicine tofacitinib (Xeljanz, Xeljanz XR). U.S. Food & Drug Administration. https://www.fda.gov/drugs/drug-safety-and-availability/fda-approves-boxed-warning-about-increased-risk-blood-clots-and-death-higher-dose-arthritis-and. Updated July 26, 2019. Accessed September 9, 2019.
3. Xeljanz (tofacitinib) [package insert]. New York, NY: Pfizer; July 2019.