DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Safety Communication

Xeljanz, Xeljanz XR (tofacitinib): Drug Safety Communication - Initial Safety Trial Results Find Increased Risk of Serious Heart-related Problems and Cancer with Arthritis and Ulcerative Colitis Medicine

The FDA is alerting the public that preliminary results from a safety clinical trial show an increased risk of serious heart-related problems and cancer with the arthritis and ulcerative colitis medicine Xeljanz, Xeljanz XR (tofacitinib) compared to another type of medicine called tumor necrosis factor (TNF) inhibitors. FDA required the safety trial, which also investigated other potential risks including blood clots in the lungs and death. Those final results are not yet available.

In February 2019 and July 2019, FDA warned that interim trial results showed an increased risk of blood clots and death with the higher 10 mg twice daily dosage, and as a result, approved a *Boxed Warning* to the tofacitinib prescribing information. The clinical trial is now complete and initial results show a higher occurrence of serious heart-related events and cancer in rheumatoid arthritis (RA) patients treated with both doses of tofacitinib compared to patients treated with a TNF inhibitor. FDA is awaiting additional results from the trial.

BACKGROUND: Tofacitinib was approved in 2012 to treat adults with RA who did not respond well to the medicine methotrexate. In 2017, FDA approved tofacitinib to treat patients with a second condition that causes joint pain and swelling, psoriatic arthritis (PsA), who did not respond well to methotrexate or other similar medicines. In 2018, FDA approved the medicine to treat ulcerative colitis, which is a chronic, inflammatory disease affecting the colon. Tofacitinib works by decreasing the activity of the immune system; an overactive immune system contributes to RA, PsA, and ulcerative colitis.

RECOMMENDATION:
Patients should not stop taking tofacitinib without first consulting with their health care professionals, as doing so may worsen their condition.

Health care professionals should consider the benefits and risks of tofacitinib when deciding whether to prescribe or continue patients on the medicine. Continue to follow the recommendations in the tofacitinib prescribing information https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=68e3d6b2-7838-4d2d-a417-09d919b43e13&audience=consumer

Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online. https://www.accessdata.fda.gov/scripts/medwatch/index.cfm
- Download form https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.

Source: https://www.fda.gov/safety/medical-product-safety-information/xeljanz-xeljanz-xr-tofacitinib-drug-safety-communication-initial-safety-trial-results-find-increased