DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Safety Communication

Janus Kinase (JAK) inhibitors: Drug Safety Communication - FDA Requires Warnings about Increased Risk of Serious Heart-related Events, Cancer, Blood Clots, and Death

ISSUE: The FDA is requiring revisions to the Boxed Warning, FDA's most prominent warning, for Xeljanz/Xeljanz XR (tofacitinib), Olumiant (baricitinib) and Rinvoq (upadacitinib) to include information about the risks of serious heart-related events, cancer, blood clots, and death.

Based on the review of a large randomized safety clinical trial, the FDA has concluded there is an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death with the arthritis and ulcerative colitis medicines Xeljanz and Xeljanz XR. This trial compared Xeljanz with another type of medicine used to treat arthritis called tumor necrosis factor (TNF) blockers in patients with rheumatoid arthritis. The trial's final results also showed an increased risk of blood clots and death with the lower dose of Xeljanz.

The FDA is requiring new and updated warnings for two other arthritis medicines in the same drug class as Xeljanz, called Janus kinase (JAK) inhibitors, Olumiant and Rinvoq. Olumiant and Rinvoq have not been studied in trials similar to the large safety clinical trial with Xeljanz, so the risks have not been adequately evaluated. However, since they share mechanisms of action with Xeljanz, FDA considers that these medicines may have similar risks as seen in the Xeljanz safety trial.

Two other JAK inhibitors, Jakafi (ruxolitinib) and Inrebic (fedratinib), are not indicated for the treatment of arthritis and other inflammatory conditions and so are not a part of the updates being required to the prescribing information for Xeljanz, Xeljanz XR, Olumiant, and Rinvoq. If FDA becomes aware of any additional safety information or data that warrants updates to the prescribing information for these medicines, the FDA may take further action and will alert the public.

BACKGROUND: Xeljanz/Xeljanz XR, Olumiant, and Rinvoq are used to treat certain serious, chronic, and progressive inflammatory conditions. All three medicines are approved to be used alone or with other drugs to treat rheumatoid arthritis, a condition in which the body attacks its own joints, causing pain, swelling, joint damage, and loss of function. Xeljanz is also approved to treat psoriatic arthritis, a condition that causes joint pain and swelling; ulcerative colitis, which is a chronic, inflammatory disease affecting the colon; and polyarticular course juvenile idiopathic arthritis, a type of childhood arthritis.

RECOMMENDATIONS:

Patients who are taking Xeljanz/Xeljanz XR, Olumiant, or Rinvoq should tell their health care professional if they are a current or past smoker, or have had a heart attack, other heart problems, stroke, or blood clots in the past as these may put them at higher risk for serious problems with the medicines. Patients starting these medicines should also tell their health care professional about these risk factors. Patients should seek emergency help right away if they have any symptoms that may signal a heart attack, stroke, or blood clot. Treatment with these medicines is associated with an increased risk of certain cancers including lymphoma and lung cancer. Patients should also talk to their health care professional if they have any questions or concerns.

Health Professionals should consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Xeljanz/Xeljanz XR, Olumiant, or Rinvoq. This is particularly the case in patients who are current or past smokers, those with other cardiovascular risk factors, those who develop a malignancy, and those with a known malignancy other than a successfully treated nonmelanoma skin cancer. Reserve these medicines for patients who have had an inadequate response or intolerance to one or more TNF blockers. Counsel patients about the benefits and risks of these medicines and advise them to seek emergency medical attention if they experience signs and symptoms of a heart attack, stroke, or blood clot.

Health care professionals, consumers 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.

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